

CLASS DETERMINATION 1-91  
IDENTITY OF IMPORTING COUNTRY UNDER FIFRA SECTION 17(A)(2)

I. BACKGROUND

Section 17(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) sets out the conditions under which pesticides not registered for use in the United States may be exported to other countries. Under that provision and the Environmental Protection Agency (EPA) statement of policy governing its implementation (45 FR 50274, July 28, 1980), a pesticide which is not registered under section 3 or sold under section 6(a)(1) of FIFRA may be exported only if, prior to export, (1) the foreign purchaser signs a statement acknowledging it understands that the pesticide is unregistered and cannot be sold in the United States and (2) a copy of the acknowledgement statement has been transmitted to EPA for sending to the government of the importing country. Under EPA's policy, these requirements apply only to the first shipment of each unregistered pesticide to a particular purchaser in a given country annually.

EPA's 1980 policy statement permitted exporters to claim as confidential business information required to be reported to EPA on the foreign purchaser's acknowledgement statement. The information required to be reported is as follows:

- (a) Name and address of the exporter;
- (b) Name and address of the foreign purchaser;
- (c) Name of the product and the active ingredient and an indication that the purchaser understands that the product is not registered for use in the United States;
- (d) Destination of the export shipment if different than purchaser's address;
- (e) Signature of the foreign purchaser; and
- (f) Date of the foreign purchaser's signature.

In the past, and in accordance with that policy statement, EPA has treated this information as confidential when so claimed by the exporter. However, EPA issued another policy statement on January 12, 1990 (55 FR 1261) addressing the confidential status of information reported to EPA under section 7 of FIFRA which necessarily affected the confidentiality of certain information reported under section 17(a)(2)

Specifically, because section 7 mandates that certain information is not entitled to confidential treatment, the fact that a company has submitted a notice under section 17(a)(2) for a given pesticide is necessarily public as well. (The active ingredient of that pesticide is also public information).

This class determination addresses the confidentiality of the identity of the importing country of the unregistered pesticide export. It does not address the status of information about the

foreign purchaser, information reported about research and development products, or quantity of shipment information which may be recorded on the purchaser acknowledgement statement.

## II. FINDINGS

Under EPA's regulations on business confidentiality at 40 C.F.R. 2.207, I have authority to issue class determinations concerning entitlement of business information to confidential treatment. In the case of the information reported to EPA under FIFRA section 17(a)(2) concerning the identity of importing country I have found:

(1) EPA possesses numerous notices filed under FIFRA section 17(a)(2) and will continue to receive such notices in the future.

(2) The information reported concerning importing country is of the same nature and therefore can be treated similarly for the purpose of this determination.

(3) A class determination will serve a useful purpose by simplifying EPA responses to Freedom of Information Act (FOIA) requests for information contained in the notices, reducing the burden of individual determinations and informing requesters and affected businesses of EPA's position in advance.

EPA may withhold information from disclosure under the FOIA if the information falls within one of the exemptions in the Act. One exemption is for "trade secrets" and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. 552(b)(4). The matter to be decided in this class determination is whether the identities of importing countries reported under FIFRA section 17(a)(2) are entitled to be withheld from disclosure under this exemption of the FOIA.

The information in question is clearly commercial information obtained from a person. The issue is whether this information is trade secret or otherwise confidential within the meaning of 5 U.S.C. 552(b)(4) and EPA's business confidentiality regulations at 40 C.F.R. Part 2, Subpart B.

Before EPA may conclude that information is exempt from disclosure as trade secret or confidential commercial information, the Agency must find that the information is in fact maintained in confidence by the business and is not publicly available. If it is not maintained in confidence or is publicly available, it is not entitled to confidential treatment and EPA must disclose the information.

The weight of evidence shows that destination information on unregistered pesticides is publicly available for many such exports. For example, some countries publish lists identifying monthly imports including information on the name or type of pesticide, the exporting country and the exporting company. Other

countries make this information available on request.

Also widely available is information on international markets for particular pesticides. There is widespread advertising by United States exporters on billboards and in stores in foreign countries for pesticides sold in those countries but not registered in the United States. Similar advertising appears in domestic and foreign publications.

There also exist compilations listing pesticides and their regulatory status throughout the world, such as three volumes published jointly by the Agricultural Requisites Scheme for Asia and the Pacific and the International Co-operation Centre for Agricultural Research and Development covering Asia, the Pacific, and Africa.

In addition, considerable information on destination of pesticide exports is available from private publishers at a cost which is high but not prohibitively so for pesticide manufacturers. For example, Battelle publishes "World Pesticide Programme" reports which provide detailed information on pesticide use in foreign countries. "Agrow World Crop Protection News" offers market planning and development information and lists pesticides registered in various countries.

Finally, the Port Import/Export Reporting Service (PIERS) database of the Journal of Commerce provides information on all shipments leaving the United States. Information available to customers of PIERS varies in the level of detail provided, but may include commodity exported, manufacturer or shipper, destination and quantity.

Therefore, it appears that in many instances destination information on unregistered pesticide exports is not maintained in confidence and is in fact available to the public. For those exports, destination information is not entitled to confidential treatment by EPA. Since this determination must cover all notices received under section 17(a)(2), however, it is necessary to continue the confidentiality analysis to apply to those exports for which destination information may in fact be held in confidence.

Information that has been kept in confidence may be entitled to confidential treatment under 5 U.S.C. 552(b)(4) if it meets one of the tests set out in National Parks & Conservation Association v. Morton, 498 F.2d 765 (D.C. Cir. 1974). Under Morton, commercial or financial information may be withheld from disclosure if revealing the information would be likely (1) to impair the ability of the government to obtain necessary information in the future or (2) to cause substantial harm to the competitive position of the submitter of the information.

The first test is not applicable to export destination information because such information is required to be submitted to EPA under FIFRA 17(a)(2) and EPA's policy statement. Therefore,

the information is not voluntarily submitted and EPA's ability to obtain it in the future would not be impaired by disclosure. Accordingly, the applicable Morton test is the second one, whether disclosure of this information would be likely to cause substantial harm to the competitive position of the submitter.

Country of destination information other than information concerning pesticides in the research and development stage is not the type of information that would likely cause substantial competitive harm to a submitter if it were released. If not coupled with information about quantity shipped, the identity of the country of destination does not reveal specific information about the company's customer list or market share. While an argument can be made that releasing information concerning research products could enable competitors to learn new areas of chemistry being explored by the exporter and thwart "first to file" patent laws, no similar argument can be made for pesticides in an established market. Therefore, under the second Morton test, information identifying the country of destination of unregistered pesticide exports is not entitled to confidential treatment.

### III. CONCLUSION

For the foregoing reasons, I find that information reported to EPA under FIFRA section 17(a)(2) on unregistered pesticide exports identifying the importing country is not entitled to confidential treatment under 5 U.S.C. 552(b)(4) or FIFRA.

April 25, 1991

Date

Craig B. Annear

Craig B. Annear  
Associate General Counsel

operating a registered pesticide establishment must submit to EPA and annually update the following information:

• • • the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—(A) which he is currently producing; (B) which he has produced during the past year; and (C) which he has sold or distributed during the past year.

Subsection (d) of section 7 states that the information submitted under subsection (c) shall be considered confidential, subject to section 10 of FIFRA, except for "the names of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment • • •" (Section 10 states general rules regarding confidential business information under FIFRA and sets out categories of information which are not entitled to confidential treatment.)

It is therefore clear from the language of section 7(d) that certain information required under section 7(c) is publicly available while certain other information may not be. Specifically, the following information on the section 7 reporting form is not entitled to confidential treatment: the name and location of the pesticide establishment, the name of the pesticide(s) produced there, and, if applicable, the name of the active ingredient(s). Required information which may be entitled to confidential treatment includes the amount of pesticides produced or distributed by an establishment. Information required under subsection 7(c)(2) concerning recipients of pesticides may also be entitled to confidentiality.

EPA is issuing this notice clarifying its interpretation of section 7 because the current section 7 reporting form (EPA Form 3540-18), and instructions for the form, incorrectly tell submitters that all information reported on the form will be treated as confidential. The form and instructions will be reissued in the near future in a corrected version that will state which information is not entitled to confidentiality under section 7. In clarifying its policy, EPA is hereby providing a 30-day comment period, at the end of the comment period EPA will consider the information described above as publicly available.

Section 17(a)(2) of FIFRA allows the export of unregistered pesticides to foreign countries if, prior to export, the foreign purchaser has signed a statement acknowledging that he or she understands that the pesticide is not registered for use and cannot be sold in the United States. In accordance with

section 17(a)(2) and established EPA policy, the exporter must provide that statement to EPA, and EPA then transmits it to an appropriate government official of the importing country. Because section 7(d) requires disclosure of the names of pesticide products produced by an establishment in a given year, whether registered or unregistered, and because names of producers of registered pesticides are a matter of public record under FIFRA section 3, the fact that a company makes a given unregistered pesticide is therefore also a matter of public record. Accordingly, since unregistered pesticides generally may be made only for the export market, the fact that a company has filed a notice under section 17(a)(2) for a given pesticide will also be public information.

EPA is hereby also providing 30-days notice that the filing of a notification of export under section 17(a)(2) for a given unregistered pesticide will not be entitled to confidential treatment. EPA will treat the following information contained in a section 17(a)(2) notice as public: the identity of the producer of the unregistered pesticide; the identity of the exporting company; the name of the unregistered pesticide product; and, if applicable, the name of the active ingredient. EPA is still considering whether other information provided under section 17(a)(2), such as the name of the country of export, should be entitled to confidentiality.

Dated: December 29, 1989.

Linda J. Fisher,

*Assistant Administrator for Pesticides and Toxic Substances.*

[FR 90-746; Filed 1-11-90; 8:15 am]

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[OPP-7001; FRL-3688-1]

#### **Nonconfidentiality of Certain Information Submitted under Sections 7 and 17(a)(2) of FIFRA**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** Under section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), certain information required to be reported to EPA by pesticide producers is not entitled to be treated as confidential business information. Specifically, in accordance with the statute, EPA considers as public information the name and location of the pesticide establishment reported, the names of any pesticides produced, sold, or distributed, and, if applicable, the names of active ingredients used. EPA also considers as nonconfidential certain information required to be reported under FIFRA section 17(a)(2) regarding export of unregistered pesticides. Specifically, the fact that a section 17(a)(2) export notification has been submitted by a company concerning a given pesticide is public information based on the information required to be disclosed under section 7.

**DATE:** The information described as nonconfidential will be considered public on February 12, 1990.

**FOR FURTHER INFORMATION CONTACT:** Michael C. Calhoun, Compliance Division (EN-342), Office of Compliance Monitoring, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (202) 382-3809.

**SUPPLEMENTARY INFORMATION:** Under section 7 of FIFRA (7 U.S.C. 136 to 136y), subsection (c)(1), any producer

P17

Monday  
July 28, 1980

# Federal Register

## Part VI

## Environmental Protection Agency

### Statement of Policy on the Labeling Requirements for Exported Pesticides, Devices, and Pesticide Active Ingredients and the Procedures for Exporting Unregistered Pesticides

## ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, and 180

[FRL 1546-5]

### Statement of Policy on the Labeling Requirements for Exported Pesticides, Devices, and Pesticide Active Ingredients and the Procedures for Exporting Unregistered Pesticides

**AGENCY:** Office of Enforcement, Environmental Protection Agency (EPA or the Agency).

**ACTION:** Notice of policy statement.

**SUMMARY:** The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act) was amended by the Federal Pesticide Act of 1978 on September 30, 1978. Section 17(a) of the Act was modified so that pesticides, devices, and active ingredients used in producing pesticides which are manufactured for export must now bear certain minimal labeling, and the producers of such products are now subject to the requirements of both FIFRA sections 7 (establishment registration) and 8 (books and records). In addition, unless a pesticide is registered under section 3 or is being sold under section 6(a)(1) it cannot be lawfully exported unless, prior to export, (1) the foreign purchaser has signed a statement acknowledging that the purchaser understands that the pesticide is unregistered and therefore cannot be sold in the United States, and (2) a copy of that statement has been transmitted to EPA for transmittal to the appropriate officials of the importing country. This foreign purchaser acknowledgement statement must be acquired by the exporter and transmitted to EPA for the first shipment of each unregistered pesticide to a particular purchaser for each importing country, annually.

This notice informs the public of the scope of the new labeling requirements and of the procedures that an exporter of unregistered pesticides must follow to acquire acknowledgement statements which will be transmitted by the U.S. Government to the government of the importing country.

**EFFECTIVE DATES:** *Labeling.* Labeling requirements for exported pesticides, devices, and pesticide active ingredients became effective March 29, 1979, (Federal Pesticide Act of 1978, Pub. L. 95-396, 92 Stat. 833). Therefore, exported products which fall within the purview of this notice must now bear labels which comply with the statutory requirements of FIFRA section 17(a)(1).

*Purchaser Acknowledgement Statements.* After thirty days from the date of this notice, exporters of unregistered pesticides will be in violation of FIFRA if the foreign purchaser acknowledgement statements have not been acquired before shipment and transmitted to EPA in accordance with this policy.

**FOR FURTHER INFORMATION CONTACT:** John J. Neylan III, Office of Enforcement, Pesticides and Toxic Substances Enforcement Division (EN-342), EPA, 401 M Street, S.W., Washington, D.C. 20460 (202) 755-1212.

**SUPPLEMENTARY INFORMATION:** On Wednesday, July 18, 1979, EPA's Office of Enforcement published a proposed statement of policy on the labeling requirements for exported pesticides, devices, and pesticide active ingredients and the procedures for exporting unregistered pesticides, [44 FR 41855]. That proposed policy statement explained in some detail what information would be required to appear on the labels or labeling of pesticides, devices, or pesticide active ingredients destined for export in order to be considered in compliance with the law. It also described the procedures for acquiring from a foreign purchaser of unregistered pesticides a statement in which the purchaser acknowledges the registration status of the pesticide. Both of these requirements became effective 180 days after the date of enactment of the Federal Pesticide Act of 1978 (March 29, 1979).<sup>1</sup>

The July 18 notice invited the public to comment on the proposed policy before September 17, 1979. Twenty-three comments were received. Following is a summary of the major modifications to the policy statement made as a result of the comments.

(1) A more detailed explanation was included of which products will be considered as not registered for use in the United States, for purposes of this policy statement.

(2) The policy statement explains in greater detail what labeling is expected to appear on exported pesticides, devices, and pesticide active ingredients.

Appendix A contains summaries of the comments made to the July 18, 1979 policy statement and the Agency's response to them.

Accordingly, the Office of Enforcement's general statement of policy on the labeling requirements for exported pesticides, devices, and pesticide active ingredients and the

procedures for exporting unregistered pesticide are set forth below.

Dated: July 10, 1980.

Jeffrey G. Miller,  
Acting Assistant Administrator for Enforcement.

## I. Summary of Policy

Pesticides, devices, and active ingredients used in producing pesticides which are manufactured for export must now bear labeling which will serve to both identify the product and the producer and to protect persons who come in contact with the product. Certain of the label items must be written in both the English language and in the language of the importing country. These bilingual labeling requirements apply to the product's ingredient statement and its warning and precautionary statements. Exporters of pesticides which are not registered for use in the United States (in accordance with this policy) must obtain a statement from the foreign purchaser of the pesticide in which the purchaser acknowledges the registration status of the product. The pesticide must also bear labeling to indicate that it is not registered in the United States. For purposes of this policy an unregistered pesticide is one which (1) contains an active ingredient not found in a federally registered product; or (2) bears labeling for a use which is currently subject to denial or cancellation of registration; or (3) is not similar in composition and use pattern to a federally registered product.

The acknowledgement statement must (1) identify the purchaser, the exporter, the product's identity and the product's destination; (2) be obtained for the first shipment of a particular pesticide to a particular purchaser for each importing country, annually; (3) be obtained before exportation takes place; and (4) be transmitted to EPA within seven (7) days of receipt by the exporter.

## II. Labeling Requirements

Section 17(a) of FIFRA has been amended to provide as follows:

(a) Pesticides and Devices Intended for Export.—notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act—

(1) when prepared or packaged according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q)(1)(A), (C), (D), (E), (G), and (H), 2(q)(2)(A), (B), (C)(i) and (iii), and (D), 7, and 8 of this Act;

<sup>1</sup> Pub. L. 95-396, 92 Stat. 819, September 30, 1978, Section 18(b).

Every exported pesticide, device, and active ingredient used in producing a pesticide must bear a label or labeling in English or in the language of the importing country, which meets the requirements of FIFRA section 17(a)(1). In addition, certain information which will satisfy FIFRA sections 2(q)(1)(E), (G), and (H) and 2 (q)(2)(A) and (D) must also appear on the label or labeling so as to provide bilingual (in other words, in English and in the language of the importing country) information to anyone who handles or comes in contact with these products. Any language in which official government business is conducted in the country or which is the predominately spoken language of the country, is acceptable as the second language on the label.

Pursuant to Section 17(a)(1), all exported pesticides, devices, and active ingredients used in producing pesticides must bear labels or labeling which:

- (a) bear EPA Establishment Numbers;
- (b) have ingredient statements;
- (c) have the name and address of the producer or registrant;
- (d) have statements of net weight or measure;
- (e) if highly toxic, bear skull and crossbones and statements of practical treatment in case of poisoning;
- (f) include warning and caution statements;
- (g) do not make false representations;
- (h) are not in imitation of other products; and
- (i) in the case of unregistered pesticides, bear the statement "Not Registered for Use in the United States of America." All such required statements must be conspicuous and readable.

To satisfy FIFRA section 2(q)(1)(E), the labeling provisions set forth below must appear in the English language and in the language of the importing country. This section specifies that required statements must be represented "... in such terms as to render it likely to be read and understood by the ordinary individual ...". Therefore, the following information must appear bilingually on exported product labeling:

- (a) the warning and caution statements;
- (b) the ingredient statement;
- (c) where required, the word "poison" and the statement of practical treatment; and
- (d) the statement "Not Registered for Use in the United States of America."

The following may provide more specific guidance on particular elements which must appear on the label or labeling of each exported product:

a. *EPA Establishment Number.* The Establishment Number may appear

anywhere on the label or immediate container in accordance with the establishment registration labeling requirements set forth in 40 CFR § 162.10(f).

b. *Precautionary Statements.* Warning or caution statements must be bilingual and must be adequate for the protection of persons handling the pesticide, particularly with respect to general toxicological hazards and environmental, physical, or chemical hazards. Where the bilingual translation is obviously inappropriate to protect residents of the importing country, (for example, where a label calls for a gas mask meeting the specification of the U.S. Bureau of Mines) an equivalent caution may be substituted.

c. *Unregistered Products.* Labels of pesticides which are not registered under FIFRA (See *Products Subject to the Requirement for an Acknowledgement Statement* below) must prominently display the following statement: "Not Registered for Use in the United States of America." This statement must appear bilingually.

d. *Ingredient Statement.* The ingredient statement must appear bilingually unless the ingredients are easily identifiable despite their being listed in a foreign language.

e. *Use Classification Statement.* The statement of use classification (Restricted Use Pesticide or General Use Pesticide) must appear on the labeling of the pesticide; however, summary statements regarding the terms of the restriction, e.g., "For retail sale to and application only by Certified Applicators ..." are not required.

f. *Identity of Parties.* Name and address of the producer, registrant, or person produced for must appear in the labeling.

g. *Net Weight.* The net weight must appear on the labeling in either conventional English units or metric units.

h. *Highly Toxic Pesticides.* If the pesticide is highly toxic, the skull and crossbones, the word "Poison", and a statement of practical treatment must appear on the labeling. The word "Poison" and the statement of practical treatment shall be bilingual. The skull and crossbones may be in red or black. For guidance on what pesticides are highly toxic, see 40 CFR § 162.10 (h).

The Agency is concerned that labeling required by FIFRA not conflict with labeling requirements of the importing country. Such a situation might arise, for example, where pesticides are being exported to a foreign country with strict labeling and registration laws such as this country has. To avoid such potential conflicts, yet still meet the statutory

requirements of FIFRA, exporters may use supplemental labeling. Pesticides, devices, and active ingredients used in producing pesticides may, therefore, bear a label with the appropriate information required by FIFRA section 17(a)(1) or may be accompanied by supplemental labeling in instances where FIFRA required labeling is in contravention of foreign labeling requirements. Supplemental labeling may be attached to or accompany the product container or shipping container.

### III. Foreign Purchaser Acknowledgment Statement

Section 17 of FIFRA has been further amended to provide as follows:

(a) *Pesticides and Devices Intended for Export.*—Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act—

(2) In the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of this Act, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under the Act. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

This notice also delineates what pesticide products are affected by this provision and procedures EPA believes would satisfy the purposes of section 17(a)(2).

### IV. Products Subject to the Requirements for an Acknowledgment Statement

Many pesticides which are produced in the United States solely for export contain active ingredients that are also registered as components of pesticides used within the United States. However, the export formulations in many cases contain slightly different percentages of active ingredients and are labeled differently. Several factors dictate these minor modifications in formulation and labeling, such as different systems of measurement, pests to be controlled which are different from those for which the same or a similar pesticide product is used in the United States, and requirements for labeling in a language other than English.

The Agency believes that Congress did not intend the requirement for obtaining an acknowledgment statement which is applicable to "unregistered" pesticides to apply to products which are minor variations on formulations registered in the United States and which contain only active



ingredients which are registered in the United States. Rather, it is the Agency's view that the export amendments were meant to apply in cases in which either (1) an adverse decision concerning the use of the pesticide in the United States has been made, or (2) no decision has been made concerning use of the pesticide. The requirement for obtaining an acknowledgement statement from a foreign purchaser will apply to pesticide products in which:

(a) The pesticide active ingredient has been judged to pose "unreasonable adverse effects" to man or the environment, and the registrations of products with that active ingredient have been cancelled or denied; or

(b) Either, (1) no assessment or no conclusive assessment of the hazard resulting from use of the pesticide has been made by EPA (while the pesticide may have been used under limited experimental or emergency conditions), (2) the pesticide has never been registered under section 3 because registration for the pesticide active ingredient has not been sought or has not yet been granted, or (3) the pesticide is being exported for a use which is substantially different from any currently registered use of that pesticide (e.g., a pesticide which is registered in this country for use as a termiticide is exported bearing directions for use on food crops).

Consequently, the Agency interprets section 17(a)(2) to apply to:

(a) All pesticide products which contain an active ingredient that is not found in a federally registered product;

(b) All pesticide products bearing labeling for a use which is currently subject to denial or cancellation of registration (section 17(a)(2) will also apply to uses not considered by the Administrator during a cancellation or denial determination); and

(c) All pesticide products which are not similar in composition and use pattern to a federally registered product.

To be considered similar in composition and use pattern, a pesticide product must contain only the same ingredient or combination of active ingredients and must have the same category of toxicity as a federally registered product. Also, the use pattern must be similar to the use pattern of the federally registered pesticide to which it is being compared. Registrations involving changes in use patterns such as changes from non-food to food use, outdoor to indoor use, terrestrial to aquatic use, or non-domestic to domestic use, are not considered to qualify as similar use patterns. Pesticide uses which were never reviewed during a cancellation or denial of registration

determination (such as a pesticide use on a crop which is not grown in the United States) also do not qualify as a similar use.

Pesticide products which are subject to the requirements of section 17(a)(2) must also bear the label statement, "Not Registered for Use in the United States of America" stipulated by section 2(g)(1)(H) of this Act.

A pesticide product which has been registered under Section 24(c) of FIFRA will be considered as registered for purposes of this policy. A pesticide product which may be legally used only under an experimental use permit (Section 5) or an emergency exemption (Section 18) will not be considered as federally registered. Nor will a pesticide product whose distribution and use are legal in intrastate commerce because the producer has filed an application for federal registration in accordance with the procedures found in 40 CFR § 162.17. Technical grade and manufacturing use pesticides which are not federally registered will be considered as registered for purposes of this policy, if they qualify as being similar in composition to a registered formulation use pesticide, (i.e., if the products have the same active ingredients and category of acute toxicity).

#### V. Procedures

Section 17(a)(2) requires that before a pesticide which is not registered for use in the United States can be exported, the foreign purchaser of the pesticide must acknowledge in writing that he understands the registration status of the pesticide and that the pesticide cannot be sold in the United States. An exporter of unregistered pesticides must have received the required acknowledgement statement *before* the product is released for shipment. The Agency feels that requiring exporters to have in hand the purchaser acknowledgement statement before exportation takes place is the only way to assure that foreign purchasers comply with these new FIFRA export requirements. The Agency recognizes that this requirement may cause some disruption in the export of pesticides. However, any such delays will be visited only upon exporters of unregistered pesticides, and then only for the *first* shipment to a foreign purchaser, in a particular country, annually. The information required on the acknowledgement statement, along with a certification signed by the exporter, must be transmitted to the Environmental Protection Agency within seven days of receipt by the exporter, or by the date of export, whichever occurs first. The certification must state that

the shipment did not take place before the exporter had the signed acknowledgement statement in hand.

The Agency will consider the receipt of purchaser acknowledgement statements by local company representatives in foreign countries to be receipt by the exporter. Nevertheless, the information required by the acknowledgement statement must still be transmitted to EPA within seven days of receipt, or by the date of export, whichever occurs first.

Acknowledgement statements may be acquired at any time in advance of shipment. For example, an exporter that ships to the same foreign purchasers year after year may acquire at the beginning of a year all of the acknowledgement statements which are anticipated to be needed.

The Agency will transmit the acknowledgement statements to appropriate foreign officials through the Department of State. Statements will be transmitted promptly after receipt.

The Agency believes that the purpose of the purchaser acknowledgement statement is to advise foreign governments that pesticides which have been judged by the United States to be hazardous to human health or the environment, or pesticides for which no hazard assessment has been made, are being exported by U.S. producers to their country. Foreign governments may then use such information as they desire, perhaps, for example, in evaluating the risk of continued use of the pesticide in that country versus the benefits that pesticide provides. The Agency does not consider that the acknowledgement statement is primarily intended to serve as preshipment notification to foreign governments in order that they may intercept shipments of such pesticides. Nevertheless, because of the Agency's concern that acknowledgement statements reach foreign governments in a timely manner, the information contained in the acknowledgement statement will be forwarded to foreign governments promptly upon receipt by EPA.

As an information mechanism, the purchaser acknowledgement statement serves the purpose of alerting the foreign government that a certain pesticide is entering its country. The Agency believes that the first notice fulfills this purpose; repetitive notices would be of only marginal value, and in cases of a high volume of exports to a foreign country, might result in a flood of paper. After considering the administrative burdens placed on exporters, EPA, and foreign governments and the value of repetitive notices, the Agency has concluded that each exporter should

complete and have signed a purchaser acknowledgement statement, for the first shipment of a particular product to a particular purchaser for each importing country, annually. A shipment of the same product to a different purchaser or to the same purchaser for disposition to a different importing country would also trigger the requirement for obtaining a signed acknowledgement statement from the foreign purchaser. A second shipment, during the same calendar year, involving the same product, purchaser, and importing country would not trigger this requirement. Any change in the variables—different purchaser, different product, different importing country—will result in the need for obtaining a new purchaser acknowledgement statement.

In summary, the procedures that an exporter of unregistered pesticides must follow in obtaining and transmitting foreign purchaser acknowledgement statements are:

(a) The exporter must provide the foreign purchaser with instructions about the required information on an acknowledgement statement and inform the foreign purchaser that shipment of the pesticide cannot be undertaken unless the exporter has received from the foreign purchaser a properly completed, signed, and dated acknowledgement statement;

(b) The exporter must secure, prior to shipment, an acknowledgement statement which contains the information outlined in the *Required Information* section of this notice. Such a statement must be secured for the first purchase each year of a particular pesticide product by a foreign purchaser destined for a particular country;

(c) The exporter must forward the information required on the acknowledgement statement, along with the certification that exportation did not take place until a signed acknowledgement statement was received, within seven (7) days of receipt, or by the date of exportation, whichever occurs first, to the following address: Environmental Protection Agency, Pesticides and Toxic Substances, Enforcement Division (EN-342), 401 M Street SW., Washington, D.C. 20460.

Attention: Export Acknowledgement Statement.

#### VI. Required Information

As previously stated, a foreign purchaser of a pesticide which is not registered for use in the United States must sign a statement acknowledging his understanding that the product is unregistered and cannot be sold in this

country. The Agency does not intend to prescribe a format for this acknowledgement statement. However, the statement must include the following information:

(a) Name and address of the exporter;

(b) Name and address of the foreign purchaser;

(c) Name of the product and the active ingredient and an indication that the purchaser understands that the product is not registered for use in the United States;

(d) Destination of the export shipment, if different than purchaser's address;

(e) Signature of the foreign purchaser; and

(f) Date of the foreign purchaser's signature.

#### VII. Confidentiality

Persons submitting the information specified in Part VI may assert a claim of business confidentiality by marking this information as "FIFRA Confidential Business Information." Information so marked will not be disclosed, with the exception of disclosure to the foreign government, except in accordance with the procedures set forth in 40 CFR Part 2, 7 USC 136h, and this policy statement. If such claim is not asserted, EPA may disclose the information to the public without providing notice of disclosure or an opportunity to object.

Notwithstanding any claim of confidentiality, the acknowledgement statement will be forwarded to the appropriate foreign government in its entirety as required by section 17.

#### VIII. Relationship to Other Statutory Requirements

Producers of pesticides, devices, and active ingredients used in producing pesticides which are intended for export are subject to the establishment registration procedures, including the report requirements, as well as the record keeping requirements of FIFRA. The Agency has proposed amendments to the regulations which are promulgated under the authority of those parts of the Act (sections 7 and 8) to bring them into conformity with the newly amended FIFRA. These regulations are found at 40 CFR Part 167 and Part 169, respectively.

Pesticides, devices, and pesticide active ingredients for export are not considered to be in violation of FIFRA when produced according to the directions of the foreign purchaser, when properly labeled and, in the case of unregistered pesticides, when the foreign purchaser has signed a statement in which he acknowledges that he understands the registration status of the pesticide and the exporter

has forwarded the statement to EPA.

Exported pesticides, devices, and active ingredients used in producing pesticides which do not bear labels or labeling in compliance with FIFRA section 17(a)(1) will be considered to be misbranded. Exporters of such products will be subject to civil or criminal liabilities for violation of FIFRA sections 12(a)(1) (D) or (E)—misbranding. Exporters of unregistered pesticides will be subject to civil or criminal liabilities for violation of FIFRA section 12(a)(1)(A)—selling or distributing a pesticide which is not registered—if they fail to secure, prior to export, a properly completed, signed, and dated acknowledgement statement from the foreign purchaser of the pesticide. Falsification of the required certification may subject an exporter to sanctions under 18 U.S.C. 1001.

#### Appendix A.—Significant Comments and Responses

##### General Comments

Comment No. 1. Applicability of Rulemaking Procedures. Two commenters stated that the Agency should have implemented the export provisions of FIFRA through the procedures established by the Administrative Procedures Act for the promulgation of "substantive" rules. The Agency disagrees. As mentioned previously, these requirements for export labeling and purchaser acknowledgement statements were statutorily effective March 29, 1979, 180 days from enactment of the Federal Pesticide Act of 1978. The law lists the type of information required on an exported pesticide's labeling and the legislative history makes it clear that purchaser acknowledgement statements are to be transferred to foreign governments in the same manner that cancellation notices are furnished. The Agency's position, therefore, is that there is no need for rulemaking but rather there is a need for a general statement of policy on such matters as: (a) what would constitute minimally acceptable labeling, (b) how such labeling could be attached or accompany shipments, and (c) how foreign purchaser acknowledgement statements are to be transmitted to foreign governments.

Comment No. 2. Use of Suspended and Cancelled Pesticides List. Another commenter suggested that foreign countries can be adequately informed of the hazards of U.S. manufactured pesticides through an expansion of the Suspended and Cancelled Pesticides List. This is not the intended function of the Suspended and Cancelled Pesticides List. That list constitutes only a guide

for Government officials; it is not the final authority on the status of a given pesticide. It is the intent of Congress that the procedures that are followed for notifying foreign governments of the suspension or cancellation of pesticides be those which are also used to inform them that an unregistered pesticide will be entering their country. Therefore, the channel of communication described in this policy is derived from the procedures already used to notify foreign governments of major suspension or cancellation actions.

**Comment No. 3. Scope of the FIFRA Section 17 Requirements.** A number of commenters addressed the definition contained in this policy statement of an unregistered pesticide. The Agency agrees that clarification on this point is necessary. It is not EPA's intent to limit export of a chemical if it is properly labeled and the exporter complies with the procedures for obtaining and transmitting to EPA a properly executed acknowledgement statement. A more detailed explanation of which products will be regarded as unregistered for the purposes of this policy has been given. One commenter objected to including products with denied or cancelled uses and products with different composition or use patterns with products which contained no registered active ingredient. In drafting this policy statement, EPA adopted a broad interpretation of the registration status of a pesticide.

The Agency could have required exporters of all pesticide products that were not registered under section 3 to acquire an acknowledgement statement from the foreign purchaser. The effect of this would be that an acknowledgement statement would have been required for the overwhelming majority of exported pesticides since most exports differ slightly in formulation or directions for use from the U.S. registered product, or the labels are written in a foreign language. The EPA clearly stated in the proposed policy statement that in its view Congress did not intend that exported products with minor variations from EPA-registered pesticides be subject to the export notification procedures. However, products with cancelled uses or with substantial differences in composition or use patterns cannot be considered products with minor variations. The Agency must, therefore, reject this comment.

**Comment No. 4. Status of Certain Unregistered Pesticides.** One commenter suggested that experimental use products be treated as registered products; another commenter thought that products with temporary tolerances

should be considered as if they were registered. Since registration data for such products are not complete, it has consistently been Agency policy to treat experimental use products and products with temporary tolerances as unregistered products. Products which bear registrations under section 24(c) of FIFRA will, however, be treated as registered products. Products undergoing Rebuttable Presumption Against Registration will be considered in accordance with their registration status at the time of export. It was suggested by one commenter that those pesticides which were registered by a foreign country should not be subject to the requirement for an acknowledgement statement. In order to adequately enforce a policy which took this approach, the EPA would have to evaluate the internal registration procedures conducted by other countries and to regulate exports based upon the policies of the *importing* country. Thus, EPA policy would be different for similar shipments going to different countries. The Agency rejects this comment. Not only would it be administratively difficult to operate such an export program, but such a policy fails to recognize the point of having the acknowledgement statement: To inform foreign governments of the U.S. registration status of a pesticide.

**Comment No. 5. Non-Commercial Exportation.** Another commenter requested clarification on the application of the notice provision to pesticides which are exported without a commercial transaction. There are two possible categories of products to which this comment might apply: the first would be small amounts of pesticide exported for research purposes only; the second would be large shipments exported to a foreign establishment of the domestic company which manufactures it. Research quantities are subject to the labeling rules of this policy but not to the acknowledgement statement requirement. Large shipments transferred from a domestic facility to a foreign facility of the same company will be treated in accordance with their U.S. registration status. That is, if the product is registered (in accordance with the use of that term in this policy), no acknowledgement statement is required; if the product is not registered, an acknowledgement statement will be required.

**Comment No. 6. Technical and Multiple Use Chemicals.** Some commenters asked for clarification of the impact of this policy upon formulated and technical grade products and multi-use products. Formulated and

technical grade products which are subject to FIFRA are subject to this policy. The label on the exported product must comply with section 17 of FIFRA. A multi-use product for which no pesticide claims are made and which is not an active ingredient in any pesticide product in the United States is not subject to this policy, even if it is subsequently processed into a pesticide in another country.

#### Labeling Comments

**Comment No. 7. Use of Bilingual Labeling.** A number of commenters stated that the law did not require bilingual labeling. The law states that an exported pesticides, device, or pesticide active ingredient must bear labeling in conformance with FIFRA section 2(q)(1)(E). The FIFRA states in section 2(q)(1)(E) that a pesticide is misbranded if:

Any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon . . . in such terms as to render it *likely to be read and understood by the ordinary individual* under customary conditions of purchase and use; (Emphasis added.)

The EPA interprets this passage to apply to ordinary individuals in the importing country as well as in the United States. Thus, the bilingual requirements are meant to communicate some basic information about the product to as many handlers of the pesticide as possible. International symbols, suggested by one commenter, could not adequately communicate all the required label elements, although they may be used in addition to the required wording. Commenters asked for guidance regarding EPA's enforcement of the bilingual requirement in two specific instances: when the importing country has several official dialects, or when English is an official government language. Any language in which official government business is commonly conducted in the country, or which is the predominately spoken language of the country, is acceptable as the second language on the label. If English is one of these languages, then a bilingual label is optional, except as may be required by the importing country. One commenter asked if a translation of the U.S. label would be satisfactory. Such a label would be acceptable if the necessary elements appeared both in English and in the foreign language.

**Comment No. 8. Foreign Labeling Requirements.** Several commenters asked about the application of this policy to labels which comply with the laws of the importing country. It is not

the intention of this policy to supersede the labeling requirements of foreign governments. However, FIFRA now requires that exported pesticides, devices, and pesticide active ingredients bear certain minimal labeling. If the labeling which currently appears on exported pesticides does not meet the minimum FIFRA requirements, even though it may meet the foreign country's requirements, additional labeling must be added to satisfy U.S. law.

**Comment No. 9. Supplemental Labeling.** Several commenters suggested that supplemental labeling be liberally allowed. The Agency intends to be as flexible as possible in this respect. Exporters will be permitted to use a variety of types of labeling to comply with the FIFRA export requirements. The Agency's principal interest will be to ascertain that products to which this policy applies bear labels or labeling which, taken together, conform to the FIFRA section 17(a)(1) requirements.

**Comment No. 10. Establishment Numbers.** One commenter requested the option of substituting another code for the EPA Establishment Number on the label. The Act clearly requires that an Establishment Number appear on the label. The Agency must reject this suggestion since permitting other means of identifying the production establishment would negate the usefulness of such numbers.

**Comment No. 11. Restricted Use Pesticides.** Several commenters requested guidance on label requirements for exported restricted use pesticides. If the product is a restricted use pesticide, then the statement "Restricted Use Pesticide" must appear on the label or labeling. The supplementary statement of the terms and conditions of restriction is not required.

#### Acknowledgment Statement

**Comment No. 12. Prior Possession of Acknowledgment Statements.** A number of commenters questioned the requirement that the acknowledgment statements be in the exporter's possession before shipment of the pesticide can take place. Other commenters stated that in their opinion foreign importers, through oversight or bureaucratic inefficiency, will not comply with the acknowledgment statement requirement. In the proposed policy statement, the Agency clearly recognized the problem of non-compliance by foreign importers. For this precise reason, EPA must reject the contention that acknowledgment statements should not be required to be in the exporter's control *before* shipment can take place. A more liberal

interpretation of what constitutes receipt of the acknowledgement statements has been provided in the final policy statement to facilitate compliance. One commenter suggested that a signed acknowledgement in the hands of a local company representative be considered a receipt by the exporter. The Agency agrees that this would be acceptable so long as the information required on the acknowledgement statement is sent to EPA within the stated time period. If a company anticipates several orders in a year, the acknowledgement statements may be obtained in advance of the actual order. One commenter stated that the requirement that acknowledgement statements be sent to EPA within seven days of receipt by the exporter was too restrictive. This commenter suggested that transmittal of the acknowledgement statement should be tied to the date of shipment. The Agency disagrees. Where possible, acknowledgement statements will be sent to foreign governments as far in advance of shipment as possible. This will provide the government some time to review the information received. The Agency feels more timely notification will occur if transmittal of the acknowledgement statement is tied to date of receipt.

**Comment No. 13. Certifications.** Some commenters objected to filing, along with the acknowledgement statement, a certification that the order was not shipped before the acknowledgement statement was received. The Agency believes that a certification statement is necessary. While some monitoring of compliance will be through inspection of required books and records, a certification requirement will serve to remind exporters that shipment must wait until the acknowledgement statement has been received.

**Comment No. 14. Destination of Shipment.** One commenter suggested that there was no need to include in the acknowledgement statement the destination of the export shipment, if different than the purchaser's address. This comment is rejected because without this information the Agency would be unable to determine if the labeling complied with the bilingual requirements nor would it know the proper place to send the acknowledgement statement.

**Comment No. 15. Annual Reporting.** Several commenters stated that the requirement that a new acknowledgement statement be acquired each year that a particular product is exported is overly burdensome. They point out that the law requires an acknowledgement statement

only once per country, not once per country, per year. The Agency must reject this comment. Although FIFRA is not clear on this point, the law seems to indicate that an acknowledgement statement should be acquired for each export shipment of an unregistered pesticide. It is the Agency's position that imposing such a requirement would be a burden for all parties concerned—exporters, importers, and the U.S. Government, as well as foreign governments—beyond any regulatory purpose it may serve. The requirement to send an acknowledgement statement once per year, which is similar to that being considered under the Toxic Substances Control Act, is not overly burdensome, and yet accomplishes the purpose of regular notification to foreign governments.

**Comment No. 16. Notification of Foreign Governments.** Several commenters questioned the procedure for notifying foreign governments. It was suggested that either the foreign purchaser or the exporter should directly notify the foreign government. The EPA rejects this proposal. First, it would be difficult, if not impossible, for the Agency to monitor compliance under such a procedure. Second, as previously explained, the procedure for transmitting acknowledgement statements parallels that of the notification of foreign governments of suspended or cancelled registrations. It is the understanding of the Agency that such a procedure, namely government-to-government contact, was the intent of Congress.

**Comment No. 17. Problems with Importing Countries.** Two commenters suggested that the policy be different for socialist or communist countries. These commenters cited their experience exporting pesticides to these countries where the "importer" is an agency of the government. These import agencies are said by the commenters to be staffed by very conservative bureaucrats who are reluctant to sign unusual requests. As has been discussed earlier, it is not the intent of this Agency to write a different export policy for different countries. However, should numerous problems arise with any particular country, the Agency will work with industry and the Department of State to solve them.

**Monday  
February 12, 1990**

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**Part III**

**Environmental  
Protection Agency**

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**40 CFR Part 152 et al**

**Pesticide Export Policy Review and  
Labeling Requirements for Pesticides,  
Devices, and Pesticide Active Ingredients  
Intended for Export; Proposed Policy  
Statements**

**ENVIRONMENTAL PROTECTION AGENCY**

40 CFR Parts 152, 153, 155, 156, 157, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173 and 180

[OPP-170001; FRL 3690-3]

**Pesticide Export Policy Review**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed policy statement.

**SUMMARY:** EPA is proposing to revise its pesticide export policies, and invites public review and comment on its proposals. EPA has undertaken a comprehensive review of its pesticide export policy and has examined: EPA's international notice transmittal system; the program to ensure exporters' compliance with regulatory requirements; the notification system's compatibility with international procedures; the confidential nature of information collected on pesticide exports; other international pesticide activities and their relationship to the Agency's goals in this area. This review has led EPA to propose changes in its existing export policies. EPA expects these changes to result in a program more responsive to the concerns of the U.S. public, international organizations, and representatives of other countries about international trade in and use of pesticides.

**DATES:** Comments on the proposed revisions must be received on or before May 14, 1990.

**ADDRESSES:** Submit written comments, bearing the identification number OPP-170001, by mail to: Public Docket Field Operations Division (H7506C), Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, DC 20460 U.S.A. In person, deliver comments to: Rm. 246, CM #2 1921 Jefferson Davis Highway, Arlington, Virginia.

Information submitted in any comment concerning the proposal may be claimed to be confidential by marking any or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. Comments will be available for public inspection in room 246 at the address given above, from 8 a.m. to 4 p.m.,

Monday through Friday, except legal holidays.

**FOR FURTHER INFORMATION CONTACT:** By mail: Cathleen McInerney Barnes (Project Coordinator), Office of Pesticide Programs, H7501C, U.S. Environmental Protection Agency, Washington, DC 20460 U.S.A. Office Location: CM #2, Rm. 1115, 1921 Jefferson-Davis Highway, Arlington, Virginia. Telephone: 703-557-7102. Facsimile: 703-557-8244 Telex: 202-382-7883.

**SUPPLEMENTARY INFORMATION:** This Notice containing EPA's proposed revisions to its pesticide export policy has six units. Unit I gives background information, including a profile of pesticide exports from the United States, the legal authority for regulating exports and establishing a notification system, EPA's 1980 policy statement under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), previous evaluations of the system, and reasons for the current review. Unit II describes the goals and objectives of the EPA's international activities program in the pesticide area. Unit III summarizes the proposed statement of policy for FIFRA section 17(a), which relates to the requirements for pesticide products exported from the United States; the full statement of the FIFRA section 17(a) policy is being published separately elsewhere in this Federal Register. Unit IV proposes revisions to policies under FIFRA section 17(b), which relates to world-wide notifications of EPA's regulatory actions affecting pesticides. Unit V reviews the confidentiality of export information. Unit VI describes EPA's FIFRA section 17(d) policy activities, related to international pesticide projects and programs in which EPA is engaged.

**I. Background****A. Global Pesticide Market; Exports From United States; Pesticide Usage; Agricultural Imports**

EPA estimates that 4.2 to 4.5 billion pounds of conventional pesticides (measured as active ingredients) are produced and used in the world annually. About three fourths of this (3.4 billion pounds) is used for agricultural purposes. The remainder (about 1.1 billion pounds) is used for non-agricultural purposes. The United States, along with other industrialized countries such as West Germany and the United Kingdom, is a major exporter of pesticides. In 1988, the United States exported approximately 450 million pounds of active ingredient pesticides; this figure represents approximately 30 percent of overall U.S. pesticide production, and approximately 10

percent of the total world pesticide consumption, not including wood preservatives or disinfectants. Figures compiled by the Department of Commerce place the value of U.S. pesticide exports at almost \$1.7 billion for 1988.

The United States is also a major importer of agricultural commodities. In general, imports comprise about 15 percent of total U.S. agricultural product consumption. For certain items—coffee, bananas and cocoa, for example—imports are a much higher percentage of the total U.S. consumption. Pesticides are used in the production of many of the imported food commodities that Americans consume.

As a major exporter of pesticides, and a major importer of pesticide treated foods, the United States has a great interest in ensuring that pesticides are used responsibly throughout the world. FIFRA gives EPA specific authority to enact programs designed to address issues concerning international pesticide use.

**B. Legal Authority**

Provisions of FIFRA section 17 concerning imports and exports of pesticides were first enacted in the Federal Environmental Pesticide Control Act of 1972 (Pub.L. 92-516) which amended FIFRA. The provisions for export notification (section 17(a)) were added in amendments to FIFRA through the Federal Pesticide Act of 1978, on September 30, 1978 (Pub.L. 95-396). Currently, section 17 reflects an active but somewhat limited role for EPA in the export of pesticides. The primary emphasis of this section is on the provision of information by EPA to foreign governments. Section 17 of FIFRA currently mandates two systems of notification: a notice to the government of an importing country of the export of unregistered pesticides (section 17(a)(2)) and a notice to all countries of certain regulatory control actions taken by EPA (section 17(b)). In addition, the statute (section 17(d)) directs EPA to participate in international efforts in pesticide research and regulation.

1. *FIFRA section 17(a).* FIFRA section 17(a) provides as follows:

(a) *Pesticides and Devices Intended for Export.*—Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act.

(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients



used in producing pesticides shall be subject to sections 2(p), 2(q)(1) (A), (C), (D), (E), (G), and (H), 2(q)(2) (A), (B), (C) (i) and (iii), and (D), 7, and 8 of this Act; and

(2) In the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of this Act, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

2. *FIFRA section 17(b)*. FIFRA section 17(b) provides as follows:

(b) *Cancellation Notices Furnished to Foreign Governments.*—Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 3 of this Act and that could be used in lieu of such pesticide.

3. *FIFRA section 17(d)*. FIFRA section 17(d) provides as follows:

(d) *Cooperation in International Efforts.*—The Administrator shall, in cooperation with the Department of State and any other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.

### C. Evaluations of Systems

Over the past few years, EPA has taken steps to assess the effectiveness of its notification programs under both FIFRA sections 17 (a) and (b).

1. *Evaluation in Africa: 1984.* In June 1984 an EPA official conducted research in Kenya, Senegal and Zambia on the effectiveness of EPA's programs for export notices and notices of control actions. At that time, none of the governments interviewed had received these types of notices from foreign governments other than the United States. During the 1984 review, the African officials indicated that they gave considerable weight to the regulatory decisions of EPA, and that they wished to be notified when pesticides imported from the United States were not approved by EPA. The EPA reviewer concluded that the notification systems were potentially valuable but were less effective than they could be because of difficulties in the notice transmittal process and in notice clarity. The reviewer indicated that even minor changes in the system

could greatly enhance the utility of the notices to the other governments. Many of the improvements recommended, such as providing instructions to embassies and improving the content of the control action notices, were implemented by EPA.

It is important to note that when this research was conducted, the African officials in charge of pesticides had few sources of information about the importation and use of pesticides in their countries. They welcomed the U.S. notifications as a principal source of information about pesticide imports.

2. *Evaluation in Latin America: 1987.* In August of 1987, EPA, in cooperation with the Organization of American States (OAS), conducted another evaluation of the U.S. notification systems and issued a report entitled, "Trade of Toxic Products: U.S. Notification Process and its Functioning in Selected Latin American and Caribbean Countries." The study was conducted to determine the types of information which would best suit the needs of the importing country and to evaluate the efficacy of procedures then in use by EPA in its notification processes. The study, like the one conducted in Africa, addressed both the FIFRA section 17(a) notices of export and section 17(b) notices of control action.

While noting problems in the notice transmittal process, many of the government officials who were interviewed questioned the ultimate effectiveness of any type of notification as a means of adequately addressing the problems of pesticide use in developing countries. Most government officials indicated that they would prefer to rely upon their own registration systems as the primary means of determining which pesticides should be used in their own country. They also emphasized that for any notification system to be useful, it had to supplement a domestic regulatory control program, and it had to relate to exports from all countries, rather than a select few. These points confirmed EPA's findings in the 1984 African evaluation.

The report concluded that while there were deficiencies in the U.S. notification systems, improving the notification system would not solve all of the problems related to pesticide use in the importing countries. The report recommended that issues concerning pesticide use and misuse in developing countries be addressed comprehensively, and that the United States consider providing information and assistance in many forms. It concluded that many countries need assistance in providing training and

education to pesticide users and the public about the dangers involved with pesticide use, and about the best methods of applying pesticides to minimize risk. Finally, the report concluded that many countries need assistance in developing their own regulatory programs, so that they can properly regulate all pesticides used in their country, not just those that are imported pesticides.

At the time of the report, EPA did not act to change its notification system. International discussions were underway to revise international notification systems, and the U.S. Congress was contemplating legislative changes, as well. EPA decided to wait until agreement was reached on other international systems before amending its own system. However, to address the problems identified in the 1984 and 1987 studies, EPA has offered technical advice and training to countries requesting assistance on pesticide issues. In particular, EPA has helped developing nations which often lack governmental programs to regulate pesticides.

3. *U.N. Food and Agriculture Organization (FAO) Review: 1988.* At the end of 1986, FAO circulated a questionnaire to all member governments on the implementation of the International Code of Conduct on the Distribution and Use of Pesticides. By the end of 1988, 115 countries had responded (73 percent). The questionnaire addressed each article of the Code and was designed to evaluate the status of implementation of the concepts of the Code.

Of particular interest for EPA's export policy were questions directed to Article 9, "Information Exchange," which directs member governments to implement notification systems for control actions and exports of banned or severely restricted pesticides. According to an FAO analysis of the responses, 39 of 93 developing countries did not receive information on banned or severely restricted pesticides which were in international trade. Those which did receive notice were asked to name countries which provided such information. The country most often named was the United States.

Importantly, 63 percent (57 of 91) of the developing countries reported that they did not have internal systems in place to process data on pesticides prior to importation. These responses reaffirm EPA's conclusion that improving notification procedures is not enough. Developing countries need help in establishing pesticide regulatory programs in order to understand and

utilize the information they receive on pesticides.

#### *D. Reasons For This Review*

1. *Congressional oversight.* In April 1989, the General Accounting Office issued a report to the Chairman of the Environment, Energy, and Natural Resources Subcommittee, Committee on Government Operations, of the U.S. House of Representatives, entitled, *PESTICIDES: Export of Unregistered Pesticides is not Adequately Monitored by EPA* (GAO/RCED-89-128). GAO identified problems in EPA's monitoring program regarding the section 17(a) export notification requirement and reported that foreign countries were not adequately notified on pesticides of U.S. concern pursuant to section 17(b). GAO recommended to the EPA Administrator that EPA take actions to strengthen its oversight of pesticide exports, including (1) monitoring compliance with export notification requirements; (2) changing its enforcement policy concerning the export of unregistered pesticides under section 17(a); and (3) developing criteria and procedures to improve preparation and issuance of section 17(b) notices of control actions, specifically addressing the issue of what constitutes a "significant action" on a pesticide.

Subsequently, on May 3, 1989, the Environment, Energy, and Natural Resources Subcommittee, held a hearing on the topic of pesticide exports. In addition to the issues raised in the GAO report, the Subcommittee requested that EPA officials address trends in U.S. pesticide production and exports; EPA's performance and policies relating to the implementation, monitoring, and enforcement of section 17 of FIFRA; EPA's responsibilities under the Federal Food, Drug and Cosmetic Act (FFDCA) to establish pesticide tolerances (maximum level of pesticide residue permitted on food or feed) and efforts by EPA to assist the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) in the identification of potentially adulterated food imports; U.S. involvement in international discussions relating to the Prior Informed Consent (PIC) concept; and EPA efforts to provide technical assistance to foreign countries.

EPA officials testified at the hearing that EPA's implementation of the notification procedures needed improvement and agreed to review its program and propose alternatives that would be more effective in communicating to other governments the potential risks associated with certain pesticides. EPA also indicated it had already concluded that notification

systems alone would not resolve the types of problems associated with the use of pesticides in developing countries and therefore had concentrated its limited resources on providing technical assistance. This export policy review was initiated at the conclusion of that hearing.

2. *Health and environmental concerns.* EPA has also undertaken this review in response to a growing concern among the public about the contribution of American made pesticides to health and environmental problems in the developing world. EPA, too, is concerned about the quality of the global environment and about the public health around the world, and believes that it is appropriate to reexamine its policies to see how it can better address these concerns.

Some segments of the American public have expressed the view that the United States should not permit the export of pesticides that are prohibited for domestic use. Representatives of some developing countries have expressed similar views at international meetings but no international consensus exists on this issue. EPA has based its existing policies, in part, on a number of premises. First, controlling the export of products from our country alone will not completely resolve the problems associated with pesticide misuse in developing countries. The United States is not the only country from which pesticide products are exported. Many countries, including those in the developing world, have manufacturing capabilities to produce and export the same pesticide products that have been banned or severely restricted in the United States or other industrialized countries. Second, EPA regulatory decisions are based upon risk benefit criteria for the United States, which may differ in other countries. And third, EPA believes that it may be more effective to concentrate on controlling the use of pesticide products, and assuring the availability of quality products to those wishing to use them, rather than categorically banning certain classes of U.S. pesticides from international trade.

The public has also expressed concern about the possibility of importing foods which may contain illegal residues of pesticides that can no longer be used here. This threat has been characterized as a "circle of poison." The perception is widespread that pesticides banned for use in the United States, but exported to developing countries, are returned to the United States in the form of illegal residues on imported foods. The U.S.

Government has several programs in place to address this concern.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA is responsible for setting tolerances (maximum permissible residue levels) for pesticides in or on food and feed crops. While these tolerances are established by EPA, the U.S. Food and Drug Administration is responsible for enforcing tolerances through surveillance monitoring. FDA monitors all food and feed crops, except for poultry and meat which are the responsibility of the United States Department of Agriculture (USDA).

The monitoring program consists of the collection of samples from individual lots of domestically produced and imported foods and an analysis of those samples for pesticide residues. The analytical methods used to measure the residues are generally capable of determining levels well below tolerance values. When residues in violation of tolerance levels are found in domestic samples, various sanctions such as seizure or injunction may be initiated. When violations are found in import samples, shipments may be detained at the port of entry.

When a shipment of an imported food from a particular grower or shipper is found to contain illegal pesticide residues, FDA may invoke automatic detention for future shipments of the food from that same source. While automatic detention is in effect, the importer is responsible for having each shipment of the commodity in question analyzed and certified by a private laboratory to be free of violative levels of the specific residue(s) in question. FDA frequently cooperates with states and foreign governments in its monitoring program.

The most recent statistics on FDA monitoring activities, which were compiled for Fiscal Year 1988 (October 1, 1987, through September 30, 1988), show that 18,114 samples were analyzed for pesticide residues. The analytical methods applied allowed detection of 256 separate pesticides. Imported foods represented greater than 57 percent of the total number of samples analyzed (or a total of 10,475 import samples analyzed). Of the imported samples analyzed, 62 percent had no detectable residues, less than 1 percent had over-tolerance residues, and 5 percent had residues of pesticides for which there are no tolerances for the particular pesticide/commodity combination. In cases where no tolerance existed, or where residues were over-tolerance, appropriate action was initiated.



In the past few years, FDA has placed an increased emphasis on the monitoring of imported foods. The results of this monitoring demonstrate that the dietary intakes of pesticide residues from the consumption of imported products are well below the standards set by EPA and international organizations such as FAO and the World Health Organization (WHO).

Additionally, EPA has in place a program to revoke tolerances when a pesticide's registration for a food or feed use is cancelled because of safety concerns. Revoking tolerances would likely discourage misuse as well as discourage persons in other countries from exporting, to the United States, foods bearing residues of pesticides which have been cancelled in the United States. When a notice of intent to cancel a pesticide is published, EPA's practice is to simultaneously publish a proposed tolerance revocation notice and, if possible, a notice proposing the establishment of action levels. Action levels are temporary replacement levels for tolerances which are recommended to FDA for enforcement purposes. They are usually lower than the tolerance they replace, to reflect residues presently occurring in food and feed commodities. Action levels are set because some pesticides are persistent in the environment and residues may be present in raw agricultural commodities, processed foods, and feeds for a significant time period, despite cessation of use on such commodities. As a cancelled pesticide dissipates from the environment, EPA's policy is to periodically review and lower action levels. Details on the procedures for converting tolerances to action levels are described in EPA's "Policy Statement on Revocation of Tolerances for Cancelled Pesticides," (47 FR 42956, September 29, 1982).

The quality and safety of the American food supply is a high priority for EPA. EPA is reexamining its activities and policies to see if there are changes which might increase the certainty that imported foods comply with U.S. safety standards. Specifically, EPA is evaluating the effectiveness of the tolerance program under FFDCA sections 408 and 409 and has established a workgroup which is considering the compatibility of U.S. tolerances with those of the Codex Alimentarius Commission, a joint program of the FAO and World Health Organization which establishes international food safety standards.

In addition, EPA is considering the feasibility of providing additional technical assistance and training in the

regulation of pesticides to countries from which the United States imports a significant percentage of its agricultural produce in order to ensure the quality and safety of our imported foods. The criteria for targeting such technical assistance and training might include the amount and type of produce exported to the United States, the sophistication of that country's pesticide regulatory control program, the types of pesticides used on exported commodities, and whether the country has requested any assistance.

3. *International activities—prior informed consent (PIC).* Another reason for this review of export policy is to bring U.S. activities into conformity with recently developed international procedures concerning international notifications related to pesticides and other industrial chemicals. EPA seeks, to the extent possible, to make its domestic regulatory requirements consistent with the approach taken internationally, in order to enhance its effectiveness and to avoid any duplication of effort.

In 1989, the FAO and the U.N. Environment Programme (UNEP) jointly adopted procedures, known as Prior Informed Consent, for trade in pesticides and industrial chemicals which have been banned or severely restricted to augment their existing guidelines for notification and information exchange. The United States was a strong supporter and proponent of these PIC procedures. In summary, the PIC procedures require that countries banning or severely restricting a pesticide for health or environmental reasons (including voluntary withdrawals and refusal to grant first registration when these actions are taken for health or environmental reasons) notify the FAO/UNEP joint program. FAO will manage the procedures for pesticides, while UNEP will manage the program for industrial chemicals. FAO will transmit notice of the pesticide action and the reasons for the action to pesticide importing countries along with information which will assist them in deciding whether or not to continue the importation and use of the pesticide in their country.

Those importing countries which have chosen to participate in this procedure are obligated to advise the international organization as to whether they wish to continue to import and use the pesticide freely, whether they wish no further imports at all, or whether they wish imports to continue under specific conditions (e.g., only specific formulations or only for specific uses). The PIC procedure also provides a

mechanism for the importing country to request further information and technical assistance in reaching a determination.

The PIC procedures call for exporting governments, such as the United States, to take appropriate measures, within their authority and legislative competence, designed to ensure that exports do not occur contrary to the decisions of participating importing countries. The United States intends to implement these provisions to the extent possible under its current legislative authority.

With regard to ensuring that the exporting industry complies with the decisions of the importing country, EPA, which fully supports PIC, will need to work with industry, state governments and other sectors of the public to develop monitoring methods for shipments. The Agency is interested in the concept of industry compliance with the PIC program through self-policing. EPA welcomes ideas that the public may have regarding self-auditing techniques for industry, as well as any experiences it may have with monitoring similar export programs.

## II. Agency Goals For International Pesticide Activities

EPA has established goals for its international pesticide activities, and will evaluate its policies and activities in relation to those goals. EPA's principal goal is to improve the protection of the public health and the environment from unreasonable adverse effects of pesticides, both in the United States and throughout the world. Secondly, EPA intends to facilitate international trade, particularly in agricultural commodities, through the harmonization of U.S. and international standards. In pursuing this goal, the Agency will ensure that its harmonization efforts support its efforts to protect public health and the environment. EPA intends to take actions:

1. To protect the American consumer from illegal residues of pesticides on imported food products.
2. To encourage international organizations to adopt standards consistent with those of the United States and to harmonize U.S. approaches with those of other governments.
3. To inform other governments about pesticides and to assist other governments in the development of their own regulatory infrastructure to enable them to protect their public's health and environment.

4. To benefit from the work of other governments' regulatory bodies by receiving and utilizing information on their regulatory actions.

These four areas of activity are discussed in Unit VI of this Notice. In summary, the U.S. government is committed to assisting other countries in the development and implementation of programs to assure safe pesticide use, to ensuring that residues on commodities which are imported into the United States do not exceed acceptable levels and to sharing the information and technical expertise necessary to accomplish these objectives.

### III. FIFRA Section 17(a) Policies

#### A. 1980 Policy Statement

On July 28, 1980 (45 FR 50274), EPA issued, after public review and comment, a Policy Statement which informed pesticide exporters of their obligations with respect to labeling, recordkeeping, and reporting under section 17(a). These obligations are that pesticides, devices, and active ingredients used in producing pesticides which are intended solely for export must be labeled to identify the product and its manufacturer and to provide such instructions as may be necessary to protect persons who come in contact with the product. Certain of the label items must be written in both English and the language of the importing country. If the pesticide is unregistered, the pesticide label must state, "Not Registered for Use in the United States of America."

In addition, exporters of pesticides which are not registered in the United States must obtain a statement from the foreign purchaser, in which the purchaser acknowledges the registration status of the product. Upon receipt of the statement—referred to as the purchaser acknowledgement—from the exporter, EPA must send this statement to an appropriate official of the government of the importing country. EPA requires that the exporter certify to EPA that shipment did not occur prior to the exporter's receipt of the purchaser acknowledgement. When notifying other governments, EPA sends the information through the U.S. embassy in the country of import. The information that the government of the importing country receives includes: the name of the pesticide product and its active ingredient; a brief indication of its regulatory status in the United States; the name and address of the U.S. exporter; and the name and address of the importer. The notice also includes the name and address of an EPA official who can answer questions and provide

the government of the importing country with additional information.

Since repeated notices would not necessarily enhance their utility to receiving countries, EPA also determined that submission of a purchaser acknowledgement should only be required on an annual basis for the first shipment by an exporter to a particular purchaser for each importing country. Currently, EPA does not require export notification for those unregistered pesticides which EPA has determined are substantially similar in composition and use to registered products. EPA chose this approach because EPA believed that such notifications would be of little or no use to the receiving country and that such notices might be so numerous that they would lessen the impact of any other notifications dealing with serious health and safety concerns. In addition, this approach reduces the burden of both EPA and the parties receiving the notices.

#### B. Summary of Proposed Policy Changes

Elsewhere in the Federal Register today, EPA is proposing changes to the 1980 Policy Statement. This section summarizes those changes: EPA encourages interested parties to refer to that document for the details of the proposal.

During the summer of 1989, EPA conducted a number of inspections of establishments which produce and export unregistered pesticide products to determine how the current policy was working and what changes needed to be made to better implement section 17. The inspections resulted in useful information in several areas, particularly related to exporter claims that their unregistered products were "substantially similar to registered products in composition and use" and therefore exempt from section 17(a)(2) requirements. EPA found the claim difficult to validate due to lack of supporting documentation. These investigations also showed that many of the exported unregistered products are for research and development purposes, which led EPA to consider this category of products specifically in the review of the current policy.

EPA is proposing to modify or eliminate its existing exemption for the purchaser acknowledgement requirement for products which are identical or substantially similar to currently registered pesticides. If the exemption is retained, EPA is proposing that the burden of substantiating the claim remain with the exporter, and that any similarity claims be supported by documentation. EPA is considering

whether such documentation must be maintained in records which are made available to EPA, or its representative, upon request, or submitted in a report to EPA.

Second, EPA determined that additional clarification was needed regarding the applicability of the section 17(a)(1) and 17(a)(2) requirements to research and development pesticide products. The proposed guidance will include specific working definitions concerning the product's intended research use, and a requirement for affirming such intended use by the exporter in order to exempt such research and development pesticides.

Third, EPA is proposing to require purchaser acknowledgement statements be written in English, the language of the purchaser's country, and, if different, the language of the destination country, so that the foreign purchasers, and the foreign governments that receive the statements, are more likely to understand their contents and significance. EPA is also proposing that the country of final destination be identified, i.e., the intended country of use, so that the statements are not just directed to the country of persons acting as intermediaries between the exporter and the end users. EPA is also proposing to begin to send notices directly to regulatory officials in these countries. The identification of designated national authorities for the FAO PIC procedure will provide an appropriate recipient for this purpose.

Fourth, EPA is proposing to clarify the applicability of the section 17(a)(1) policy as compared to that of section 17(a)(2). It is EPA's view that the requirements of section 17(a)(1) apply to all exported pesticides, whether or not they fall within the scope of a requirement for the purchaser acknowledgement statement requirements of section 17(a)(2). And fifth, EPA is examining its present policy of requiring annual submissions, rather than submissions on a per shipment basis and is inviting comment on this issue.

EPA is also proposing clarification of the labeling requirements concerning the ingredient statements for unregistered pesticides claiming exemption because of similarity to already registered pesticides. The label for the unregistered pesticide must be as similar as possible to the labels of the registered products, in order to improve comparability of labels on exported pesticides to those of U.S. registered products. To ensure that the foreign purchaser understands its content, EPA is also proposing to require

that certain label statements be multilingual.

#### IV. FIFRA Section 17(b) Policy

EPA invites comment on a proposed revision to its policy concerning notification of foreign governments of selected regulatory actions affecting the registration of pesticide products in the United States. Such notifications are required by section 17(b) of FIFRA. Since the major objective of this review is to improve the utility of the notification process to recipients, EPA particularly welcomes comments from foreign governments.

##### A. EPA'S 1975 Notice

EPA has interpreted the section 17(b) requirement to apply to "information having international significance." The criteria to be used in making this interpretation were issued in a Federal Register notice in 1975 (40 FR 20987, May 14, 1975). In that notice, EPA indicated that notices to foreign governments would be sent under two conditions:

(1) Whenever the Agency registers, under the authority of section 3, a pesticide that contains any new active ingredient or entails a new use.

(2) When cancellation or suspension of a pesticide becomes effective and is determined to be of international significance.

In the latter instance, EPA indicated that such determinations would be made by applying general guidance on a case-by-case basis.

EPA went on to indicate what type of action would be considered to be of international significance: actions resulting from a review of the pesticide; actions resulting from findings of risk; actions resulting from decisions to reduce or revoke tolerances under the Federal Food, Drug and Cosmetic Act; actions involving issuance of a new policy applicable to the entire pesticide industry; and actions which may have widespread environmental, economic or political implications.

##### B. Current Practice

Since 1975, EPA has transmitted section 17(b) notices whenever it has taken a significant regulatory action, such as a cancellation or suspension of a registration based on the finding that the pesticide's risks outweigh its benefits. For example, EPA notified foreign governments of the emergency suspension of dinoseb due to the potential for serious reproductive effects among workers exposed. EPA has also issued notices for significant voluntary actions. For example, EPA transmitted a notice concerning the voluntary

agreement by the registrant to halt the sale of daminozide (Alar), a plant growth regulator shown to be carcinogenic in laboratory animals.

EPA, thus far, has not transmitted notices for the registration of a new pesticide or new use pattern. EPA has generally limited the notifications to cancellations or suspensions undertaken for health or environmental reasons, and to selected actions which place significant restrictions on a pesticide's use, usually at the conclusion of a Special Review. The section 17(b) notices, as currently designed, describe the regulatory action taken, discuss in general the health or environmental concerns which prompted the action, and offer to provide additional information upon request. The notices are fairly brief, about three pages in length, and are expressed in language that is intended to be easily understood by people who may not be familiar with the U.S. pesticide regulatory program.

Under the current system, EPA's Office of Pesticide Programs prepares a notice, and through the EPA Office of International Activities, sends it to the Department of State for transmittal to other governments. The State Department transmits a cable to all diplomatic posts, directing the embassy to inform the host government of the information in the cable. The embassy then contacts an appropriate government office in the host country and informs the office of the information contained in the cable. Each embassy may handle the notification differently, depending upon individual circumstances. Some notify the Environment Ministry, some inform the Agricultural Ministry, while others may inform the Foreign Ministry which then in turn is expected to inform the pesticide regulatory body. Some embassies may simply provide a copy of the cable, some may set up a meeting to discuss the notice, while others may prepare a formal diplomatic communique to transmit the information.

EPA has determined that revisions to its international notification system are warranted, based on a comprehensive review of the system's effectiveness. The development of a final policy will benefit greatly from public comment on several key areas: the scope of the international transmittals; the frequency of transmittal and content of the notifications; and the transmittal process itself. Each is discussed elsewhere in this Federal Register, together with the options considered and the proposed revisions.

##### C. Scope of Notification

1. *Types of Regulatory Decisions.* Every year EPA takes a large number of different types of regulatory actions affecting pesticide products. These actions encompass both routine, non-controversial decisions, as well as regulatory actions that involve highly contentious issues and those which address serious concerns about public health and environmental risks. Listed below are the actions on pesticide products which could be subject to the section 17(b) notification requirement, as well as actions that are not covered by section 17(b) but may be of international interest.

###### a. Cancellations and Suspensions:

1. Final suspensions/cancellations as a result of the potential to cause unreasonable adverse effects (sections 6(b) and 6(c)).

2. Proposed suspensions/cancellations (sections 6(b) and 6(c)).

3. Final cancellation for failure of a registrant to meet conditions imposed at the time of registration, usually the submission of certain required data (section 6(e)).

4. Voluntary cancellations (section 6(f)).

5. Voluntary withdrawals.

6. Cancellations for failure to pay the fees required to reregister a pesticide or maintain a registration (section 4).

7. Cancellations resulting from other reregistration activity under section 4.

8. Suspensions for failure to submit data required by EPA after initial registration (section 3(c)(2)(B)).

9. Suspensions for failure to pay the fees required to reregister a pesticide or maintain a registration (section 4).

###### b. Registrations and Denial Decisions:

1. Registrations of the first use of an active ingredient (new chemicals).

2. First food use registrations of an active ingredient.

3. First registrations of other significant new uses of an active ingredient (e.g., first indoor use, first aquatic use, etc.).

4. Registrations or amendments to registration involving uses similar to already registered uses of an active ingredient (known as me-too registrations).

5. Registration of pesticides which are substitutes for cancelled or suspended products.

6. Denial of registration for health or environmental safety reasons.

###### c. Tolerances actions:

1. Establishment of a new tolerance.

2. Exemption from a tolerance.

3. Revocation of an old tolerance.

4. Change in tolerance.

d. Reregistrations Decisions (concerning status of existing pesticides and uses):

1. Reregistration—issuance of a reregistration document outlining the conditions a registrant must meet in order to reregister a pesticide product.

2. Other reregistration decisions making health or environmental findings.

Read literally, section 17(b) could require thousands of notifications annually—every time EPA amended a registration, cancelled a registration for failure to pay maintenance fees, or cancelled a registration at the request of a registrant. In the 1975 Notice, EPA noted that the legislative history of section 17(b) indicates that notices should serve some useful purpose. EPA went on to conclude that it would not serve a useful purpose to transmit notices for all of the actions which could fall within the scope of the requirement and, in fact, that notification of routine actions would likely lessen the impact of information having international significance. This interpretation has guided EPA in its decisions to transmit notices.

2. *Factors.* While agreeing that expansion of the notification system is appropriate, a number of factors must be considered when determining which regulatory actions should be subject to the notification requirement, and in determining in which manner the information should be transmitted. Among the factors to be considered are: EPA's legislative requirements; EPA's policy goals for international pesticide activities; the need for consistency with international activities; the value of the information to the recipient; and competing demands on EPA's and other agencies' resources.

a. *Legislative mandate.* Section 17(b) specifies that, "Whenever a registration or a cancellation or suspension of the registration of a pesticide becomes effective, the Administrator shall transmit through the State Department, notification \* \* \*." EPA believes that the language of this requirement may be interpreted in a number of ways, especially when read with the intent of Congress to provide meaningful information to other countries (S. Rep. No. 92-1540, 92d Cong. 2d Sess. at 33 (1972)). EPA has determined that it is appropriate to limit section 17(b) notifications to those that will be of benefit to the recipient countries.

b. *Goals of EPA.* As part of its international activities program, the section 17(b) notification system should further EPA's international goals. Thus, the scope of the notification system must cover actions which may have an

effect on the safety of the American food supply as well as on the potential effects of a pesticide's use in a foreign country. If the United States informs other governments about pesticides it has regulated or about the establishment of new tolerances, those governments may use that information to ensure that food exported to the United States complies with U.S. regulations.

c. *Consistency with international activities.* Although the implementation details of the PIC procedure are not yet resolved, it appears that the following types of U.S. actions will require PIC notification:

1. Final suspensions/cancellations for health or environmental reasons (sections 6(b) and 6(c)).

2. Voluntary cancellations for health or environmental reasons (section 6(f)).

3. Refusal or denial of registration for health or environmental reasons (section 3(c)(6)).

FAO is continuing to define the specifics of the system's implementation. Specifically, working with UNEP's International Registry for Potentially Toxic Chemicals (IRPTC), FAO is developing PIC decision guidance documents, an initial list of pesticides to be included in the systems, and the guidelines for selecting actions on pesticides which are appropriate for inclusion in the PIC procedure. EPA will take this information into account in the development of its new export policy and procedures discussed here and elsewhere in the Federal Register notice for section 17(a).

d. *Value to recipient.* Clearly, messages about U.S. actions on pesticides should be of use to the recipient. Section 17(b) notices should be as informative as possible and relay summaries of regulatory actions of concern to other countries. EPA now has reason to believe that other governments are interested in many regulatory actions for which EPA has not issued notices in the past, actions which would not necessarily be deemed to be of "international significance." At numerous international meetings and in correspondence with EPA, representatives of other governments have expressed an interest in obtaining more information about EPA activities. They have indicated that they need to know more about the U.S. pesticide regulatory process to aid in making decisions about the application of pesticides and to develop or enhance their own regulatory programs.

The section 17(b) notification system, however, is neither the only nor always the most appropriate means of conveying information about the U.S. pesticide program to other countries.

EPA considers that its involvement in technical assistance and training activities with other governments have been of great benefit and that its notification system should complement these activities. EPA must determine what kinds of information will be conveyed most effectively through the section 17(b) notification system versus other means of providing information.

e. *Agency resources.* EPA must also consider the most effective way to achieve its goals of protecting the health and safety of people and the environment world-wide within the context of its existing resources and those of other agencies involved in these activities. Any expansion of notification activities will entail additional resources, and may lessen the resources available for domestic regulatory programs or other international pesticide activities.

However, expansion of the notification program could also enhance other EPA international education and training programs (described in Unit VI of this notice) and make overall resource expenditure more effective. For example, if EPA were to transmit notices regarding tolerances to food and feed exporting nations, it could help improve the record of compliance with U.S. tolerances on food products exported to the United States. Further, as EPA forwards information about pesticides which have been removed from the U.S. pesticide market for health or environmental reasons, EPA's efforts to promote the safe use of pesticides are enhanced. In sum, EPA wishes to distribute the resources available for pesticide export related activities so as to provide foreign countries with sufficient and prompt notification of important U.S. regulatory actions without compromising EPA's ability to conduct supplemental technical assistance and training programs.

3. *Options.* The options for issuing section 17(b) notices range from maintaining the status quo, to issuing notices for a larger number of selected regulatory actions, to issuing notices for all regulatory actions.

a. *Notices selected and issued using current case-by-case approach.* EPA has issued section 17(b) notices on major regulatory actions whenever EPA has considered it to be important to international welfare. Other governments have informed EPA that the notices currently transmitted on suspensions and cancellations are very useful for decision-making and are appreciated. The international community has also indicated, however, that they would be interested in

receiving these notices more often. Although this expression may indicate a misperception that EPA suspends or cancels pesticides for health or safety reasons more often than it does, it is clear that many governments are interested in more routine information about U.S. pesticide actions than the current system provides.

Notification of suspensions and cancellations on a case-by-case basis has been adequate only for informing the world of the most significant pesticide regulatory decisions that EPA has made. EPA believes that a broader and more consistent notification system will do more to aid foreign countries in using pesticides safely and in complying with U.S. pesticide regulations when exporting foods to the United States.

*b. Notices for selected subset of regulatory actions.* EPA's assessment of its own and other international notification systems indicates that the international community is primarily interested in receiving notices of actions taken because of health or environmental concerns. In light of EPA's goal of providing technical assistance and training to other countries so that they may develop or improve their own pesticide regulatory programs, EPA sees merit in expanding its notification system to cover all actions taken for health or environmental safety reasons and major actions which affect the availability of a pesticide active ingredient or affect FFDCA tolerances and, thus, pesticide use. Such an expansion would broaden the scope of the system to cover all actions thought to be of interest to the international community, and is consistent with EPA's international goals. Routine, administrative actions of little interest to other countries, such as minor changes in registrations or cancellations for failure to meet reregistration requirements (e.g., fees or submissions of data), would not require international notices, but could certainly be transmitted when EPA believed it to be of interest, or made available upon request.

*c. Notices for all regulatory actions.* While it is clear from the discussions EPA has had with other governments that more information would be considered helpful, EPA believes that it must use some discretion in sending notices world-wide. The effect of sending notices for every single action EPA takes may be to confuse or overwhelm other countries with information that may not always be relevant to the use or regulation of pesticides in these countries. For instance, individual notices about the

recent cancellations of about 15,000 registrations resulting only from the failure to pay the new registration maintenance fee would probably not be of international interest or utility. Similarly, a notice concerning the registration of a use pattern which is similar to one already registered is not critical information.

Further, as noted previously, sending notices for every action would mean preparing and transmitting thousands of notices annually, an enormous and impractical use of resources. EPA believes that expanding the notification system to cover virtually all pesticide actions is neither a realistic nor an effective option. Other governments have also indicated that they are not interested in learning about EPA's decisions to approve minor registration changes.

*d. Notices required under international procedures.* The international PIC notification procedures specifically call for notification on: pesticides which are banned or severely restricted for health or environmental reasons by final government actions, including refusals to register and voluntary withdrawals for health or environmental reasons. This limited set of actions was selected by members of international organizations because of an overriding interest in health and environmental risks and to prevent overloading the transmittal system with information of minor value. EPA agrees that too much information would not be of value, and could detract from the importance of notices about health or environmental risks. However, it appears that governments are also interested in many U.S. regulatory activities beyond the scope of the international system, and EPA interprets section 17(b) as permitting notice of certain actions that would not be covered by the internationally agreed procedures.

*4. Proposal.* The subset of regulatory actions subject to international transmittal should include all actions taken on the basis of health and environmental criteria so that foreign countries receive adequate information about pesticide risks. Countries should also be notified of all major actions which affect pesticide use, including actions which eliminate all registrations for an active ingredient or substantially change a pesticide tolerance. It is important for countries to be notified of these actions because removal of an active ingredient from the U.S. market or tolerance revocations may mean that other countries will no longer wish to use the pesticide or that they will no

longer be able to export, to the United States, foods that have been treated with certain active ingredient. Further, foreign countries need to be made aware that active ingredients that have lost their U.S. registration will not go through EPA's reregistration review and thus, EPA will not be conducting any new health or environmental reviews of the pesticide.

International notification is not needed for those actions which are of an administrative or routine nature and not associated with significant health or environmental risks. Therefore, EPA is proposing that section 17(b) type notices should be transmitted to other governments on the actions listed below. EPA welcomes comments on this proposal.

a. Section 17(b) type notices should be transmitted for:

1. Final suspensions/cancellations as a result of the potential to cause unreasonable adverse effects (sections 6(b) and 6(c)).
  2. Proposed suspensions/cancellations (sections 6(b) and 6(c)).
  3. Denial of a tolerance following a formal finding that risks outweigh the benefits.
  4. Denial of an application to register a product following a formal finding that the risks outweigh the benefits.
  5. Voluntary cancellations made for health or environmental reasons (section 6(f)).
  6. Voluntary withdrawals made for health or environmental reasons.
  7. Reregistration actions—issuance of a reregistration decision document (section 4(g)(2)).
  8. The establishment of a new tolerance or an exemption from a tolerance, revocation of a tolerance or exemption, or amendment of a tolerance.
  9. All registrations of a new active ingredient and (if different) the first food use registration of an active ingredient.
  10. All other actions which eliminate all or virtually all registrations for an active ingredient including:
    - i. Final cancellations for failure of a registrant to meet conditions of registration.
    - ii. Voluntary cancellations.
    - iii. Cancellations for failure to pay the fee required to reregister or maintain registration of a pesticide.
    - iv. Cancellations resulting from other activity under FIFRA section 4.
- b. No section 17(b) Notices would be prepared on a routine basis for:
1. Registrations of each significant new use of a pesticide.

2. Registrations of uses similar to existing registered uses (known as me-too registrations).

3. Suspensions for failure to submit data under FIFRA section 3(c)(2)(B) unless they result in the elimination of all or virtually all uses of an active ingredient.

4. Cancellations/Suspensions that do not result in elimination of the registration of all or virtually all uses of the active ingredient or are not taken for health and environmental reasons (e.g. voluntary cancellation of a product by a company because of insufficient funds or unwillingness to meet data requirements for reregistration).

#### D. Timing And Frequency

The timing of a section 17(b) notice should depend on the potential effect of the action taken. Actions based on health or environmental risks or other considerations vary in their degree of significance. An international announcement of the emergency suspension of a pesticide should obviously be transmitted as soon as possible, preferably at the same time the announcement is made domestically. Actions of lesser significance such as the establishment of new tolerances, exemptions or changes in tolerances or exemptions, which happen quite frequently, could be transmitted at a later time, or even consolidated into periodic summaries.

Currently, EPA sends notices of control actions within a few weeks of the domestic announcement of the regulatory action. The notice is sent once, and never repeated. EPA's current practice is not entirely consistent with notification procedures adopted by international organizations. These procedures recommend that notices of control actions be retransmitted or at least referenced in export notices.

1. *Options.* Options for the timing and frequency of transmittal of international notices include:

a. To send a notice soon after an action is taken for every action that meets EPA's international notification criteria, and never repeat them.

b. To send notices dealing with urgent health and environmental concerns immediately and prepare an annual report that repeats these notices and lists all the less urgent actions taken during the year that meet EPA's international notification criteria.

c. *Transmit all notices as soon as possible after an action is taken.* Given the expansion of the notification system that EPA is proposing, it would be impractical and unnecessary to forward an individual notice immediately after an action was taken for every action

that meets EPA's proposed notification criteria. All of the additional notices EPA plans to send would make this approach too burdensome and would not result in great benefit to the recipients.

d. *Transmit notices on major health and environmental actions immediately; compile and transmit notices for all actions annually; and include copies of notices with all transmittals of purchaser acknowledgement statements for pesticides banned in the United States.* As previously indicated, those notices of actions about pesticides which pose great potential for health or environmental harm should be transmitted as quickly as possible, ideally at the same time announcements are made domestically. Other notices, which are of interest but which do not require immediate attention, should be compiled and sent annually. Preparing an annual report on all actions, both major and minor, would conserve EPA resources (compared with issuance of a separate notice immediately after each action), would give recipients a more comprehensive view of U.S. pesticide actions, and would likely be more effective in that it would reserve immediate transmission for those actions which carry the highest risk implications. Including copies of these notices along with purchaser acknowledgement statements for banned pesticides would ensure that those purchasing the U.S. banned pesticides would have information on the basis of the U.S. action.

2. *Proposal.* EPA believes that in light of the proposed expansion of the section 17(b) notification system, the best option for the timing and frequency of transmission of notices is to transmit as quickly as possible notices for major actions based on health or environmental considerations, and then repeat them at the end of the year. A compilation of all actions determined as warranting notice should be transmitted annually. Notices should also be included with purchaser acknowledgement statements of banned pesticides. The types of notices subject to transmittal, and the timing of the notice are listed below.

a. Transmit notice as soon as possible after the action is taken for:

1. Final suspensions/cancellations as a result of the potential to cause unreasonable adverse effects (sections 6(b) and 6(c)).

2. Proposed suspensions/cancellations (sections 6(b) and 6(c)).

3. Denial of a tolerance following a formal finding that risks outweigh the benefits.

4. Denial of an application to register a product following a formal finding that the risks outweigh the benefits.

5. Voluntary cancellations made for health or environmental reasons (section 6(f)).

6. Voluntary withdrawals made for health or environmental reasons.

These actions would also be repeated in the annual compilation and for cancelled pesticides, notices would be forwarded with purchaser acknowledgement statements required under section 17(a).

b. Transmit an annual notice for:

1. Reregistration actions—issuance of a reregistration decision document (section 4(g)(2)).

2. The establishment of a new tolerance or an exemption from a tolerance, revocation of a tolerance or exemption, or amendment of a tolerance.

3. All registrations of a new active ingredient and (if different) the first food use registration of an active ingredient.

4. All other actions which eliminate all or virtually all registrations for an active ingredient including:

i. Final cancellations for failure of a registrant to meet conditions of registration.

ii. Voluntary cancellations.

iii. Cancellations for failure to pay the fee required to reregister or maintain registration of a pesticide.

iv. Cancellations resulting from other activity under FIFRA section 4.

#### E. Content of Notices

Current notices include a summary of the action taken, the health or environmental reasons prompting the action, the legislative and regulatory background for the action, and the concerns prompting the action. They conclude by offering additional information upon request, generally in the form of a Technical Support Document or a Fact Sheet.

EPA believes that while, generally, the content of the current notices is adequate for major actions taken for health or environmental reasons, these notices could be improved. Responses from other governments to EPA's notices have been mixed. Some governments have indicated that the notices are helpful, while others have indicated that the notices are hard to understand. EPA is seeking public comment on the kinds of information which should be included in the notices and the appropriate format, particularly for the annual notice that will include listings of actions taken during a calendar year. EPA intends to comply with recommendations for formats made by international



organizations when revising the EPA notices.

#### *F. Transmittal Process*

As described previously, the Department of State, through its embassies in other countries, is currently responsible for sending section 17(b) notices to foreign governments. In practice, this has proved to be a time consuming and somewhat ineffective process. All of the cables that the State Department transmits must be ordered in terms of priority, and information about domestic regulatory actions is usually of a lower priority than diplomatic activities. Further, embassies often lack sufficient staff to forward the notices quickly and to the appropriate government officials in the receiving countries. This process often delays receipt by foreign governments of information about U.S. pesticide regulatory actions.

EPA and the State Department believe that the transmittal process would be improved if the notices were transmitted directly from EPA to other governments. Therefore, the State Department has agreed that EPA should transmit notices directly while keeping the Department informed about such communications. EPA will provide the Department with copies of the notices. This agreement meets the Congressional intent of communicating with other governments while not overburdening formal diplomatic channels with technical information.

EPA plans to forward certain notices to FAO, in accordance with the PIC procedures. Further, some notices will be sent to countries both from the United States and from FAO. As a result, such procedures will provide greater assurance that the notices will be received by appropriate officials. EPA welcomes comments on its plan to transmit notices directly, with copies forwarded to the State Department.

#### *V. Confidentiality*

##### *A. Background*

In conjunction with its effort to strengthen compliance with requirements of section 17(a), EPA is reviewing its policy concerning confidential treatment of information reported in foreign purchaser acknowledgement statements.

The proposed policy statement on section 17(a) published elsewhere in today's Federal Register indicates that the following information would be included in purchaser acknowledgement statements submitted to EPA:

1. Name and address of the exporter.

2. Name and address of the foreign purchaser.

3. Name of the product and the active ingredient.

4. Statement that indicates that the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States.

5. Country of final destination of the export shipment, i.e., where the exported pesticide is intended to be used, if different from the foreign purchaser's address.

6. Signature of the foreign purchaser.

7. Date of the foreign purchaser's signature.

In the past, EPA has treated information submitted in purchaser acknowledgement statements as confidential within the meaning of its regulations on business confidentiality at 40 CFR part 2, subpart B, when such information has been claimed as confidential by the exporter.

The proposed policy statement on section 17(a) clarifies that certain information contained in purchaser acknowledgement statements will not be entitled to confidential treatment. Specifically, the fact that an exporter has submitted a notice of export under section 17(a) for a given pesticide is a matter of public record and will not be granted confidentiality. This is based on the disclosure requirements of section 7 of FIFRA, as explained in EPA's Federal Register notice of January 12, 1990 (FR). Also, active ingredients of such exported pesticides are public information in accordance with the labeling requirements of section 17(a). Therefore, Units V.A. 1 and 3 of this notice will not be considered confidential.

##### *B. Proposal*

EPA is proposing to issue a class determination under 40 CFR 2.207 concerning the confidentiality of country of final destination as reported on purchaser acknowledgement statements. Under its regulations on business confidentiality, EPA may issue a class determination where information is of a similar nature and can therefore be treated similarly for all submittals. Some exporters have claimed destination country as confidential when submitting the required acknowledgement statement. They have substantiated their claims by asserting that disclosure of such information concerning their international markets would adversely affect their position by providing competitive advantage to other pesticide exporters.

EPA's research and inquiries, however, suggest that destination

information on unregistered pesticides is already a matter of public record. Some countries, for example, publish lists identifying monthly pesticide imports, including information on the name or type of pesticide, the exporting country and the exporting company. Other countries make such information available on request.

Also widely available is information on international markets for particular pesticides. There is widespread advertising by United States exporters on billboards and in stores in foreign countries for pesticides sold in those countries but not registered in the United States. Similar advertising appears in domestic and foreign publications. There also exist compilations for pesticides and their regulatory status throughout the world, such as a volume published jointly by the Agricultural Requisites Scheme for Asia and the Pacific and the International Co-operation Centre for Agricultural Research and Development.

In addition, considerable information on pesticide exports is available from private publishers at a cost which is high but not prohibitively so for pesticide manufacturers. For example, Battelle publishes "World Pesticide Programme" reports which provide detailed information on pesticide use in foreign countries. "Agrow World Crop Protection News" offers market planning and development information and lists pesticides registered in various countries.

Finally, the Port Import/Export Reporting Service (PIERS) database of the Journal of Commerce provides extensive information on all pesticide shipments leaving the United States. Information available to customers of PIERS includes commodity exported, manufacturer or shipper, destination and quantity. (Manufacturer or shipper name is sometimes deleted but can usually be discerned from the other information reported.) Based on the foregoing, EPA believes that destination information on unregistered pesticides generally is not maintained in confidence and is in fact publicly available. Further, markets for particular pesticides in foreign countries appear to be widely known. Therefore, disclosure of country of final destination as reported under section 17(a) would not seem likely to cause substantial competitive harm to the exporter.

EPA requests public comment on its proposal to issue a class determination which would find that country of final destination in foreign purchaser acknowledgement statements under section 17(a) is not entitled to

confidential treatment. EPA also requests comment on whether a similar determination should be made for information identifying the foreign purchaser.

#### VI. FIFRA Section 17(d) Activities

Although FIFRA section 17(d) does not mandate any specific regulatory program, EPA relies on it as the statutory authority for its international activities. This is consistent with the legislative history of this paragraph which indicates a strong Congressional desire for EPA to participate in international efforts to develop improved pesticide research and regulations. (S. Rep. No. 92-838, 92nd Cong. 2nd Sess. at 28 (1972), H. Rep. No. 92-511, 92nd Cong. 1st Sess. at 27 (1971)). In addition, this section provides authority to support the U.S. participation in activities to develop infrastructure and provide technical assistance to pesticide importing developing countries as well as those countries which use pesticides and export agricultural commodities to the United States.

EPA has undertaken a number of technical assistance activities under section 17(d) of FIFRA which are designed to achieve the goals and objectives of EPA's international pesticide activities: to protect the quality of imported food; to harmonize U.S. and international standards; to support environmental protection in other countries; and to obtain information from other countries useful to the domestic regulatory program. This section will describe the activities in which EPA is engaged in the context of how they address these policy objectives.

1. *Protecting the quality of imported food.* The most direct way in which the use of pesticides in other countries can affect the United States is by the presence of such pesticides on food imported into the United States. EPA seeks to ensure that food coming from other countries does not pose risks to the American consumer. At the same time, EPA also seeks to ensure that foreign agricultural producers and exporters do not have an unfair advantage over U.S. farmers by using pesticides the United States has decided to prohibit for dietary health reasons. Pesticide tolerances apply to all crops in commerce in the United States, regardless of their origin. While FDA and USDA are responsible for monitoring the compliance of imported foods with U.S. tolerances, EPA promotes food safety by actively participating in international organizations which develop food safety

standards, such as the WHO/FAO Codex Alimentarius Commission.

Additionally, EPA has held numerous workshops for regulatory officials and agricultural exporters to ensure that other countries are aware of the U.S. requirements for tolerances. Countries which export foods to the United States need to take into consideration the U.S. tolerances when approving uses of specific pesticides within their countries. Thus far, the Agency has planned or attended sessions with growers from Mexico, Guatemala, the Caribbean countries, Chile, China, and Malaysia, and plans to speak this year to growers in the countries comprising the southern portion of South America. These sessions not only provide EPA the opportunity to inform others about U.S. pesticide regulations, but also allow the Agency to learn more about the work of other governments' regulatory practices, thereby enhancing our ability to ensure the acceptability of imported foods.

EPA intends to continue to provide direct assistance on an as-needed basis—as resources permit—and considers this practice to be an integral part of the Agency's international activities.

2. *Harmonizing U.S. and international standards.* EPA recognizes that protecting the global environment and the public health of all peoples must be a truly cooperative international effort. Through participation in the activities of international organizations, EPA promotes the development of methods and standards that are consistent with its own, and which at the same time meet the objectives of the international community. In addition, encouraging the development of sophisticated, effective environmental protection world-wide, harmonious regulatory requirements minimize unnecessary disruptions in international trade.

EPA assisted in achieving international adoption of the goals and principles of FAO's International Code of Conduct on the Distribution and Use of Pesticides. The Code establishes standards to encourage responsible international trade practices; to assist developing countries in the regulation of pesticides; to promote the safe handling and use of pesticides; and to minimize adverse effects on public health and the environment.

In the future, EPA will participate in an international meeting in 1990 in Beijing, China, on international harmonization of pesticide tolerance levels. Additionally, analysis is underway in the Agency to consider the harmonization of U.S. tolerances with those of the Codex Alimentarius

Commission, and to determine the potential impact of recent harmonization discussions in the revisions to the General Agreement on Tariffs and Trade.

3. *Supporting environmental protection in foreign countries.* EPA's efforts to assist in the protection of public health and the environment in foreign nations follow two tracks. First, EPA provides information through the notification programs mandated by section 17 of FIFRA. These notification systems, however, have their limitations. As they were never intended to supplant a regulatory system in the importing country, only to supplement one, countries having no or minimal regulatory programs will not find the information as useful as those having more rigorous programs. Moreover, purchaser acknowledgements are transmitted under FIFRA section 17(a)(2) upon the first shipment to a foreign purchaser in a year, and often do not precede the actual shipment. Therefore, an importing country cannot rely on export notices to make a judgement about volume of shipments, nor do notices give the importing government the opportunity to prohibit shipment. Further, they report a transaction on a chemical from only one country (the United States), when other countries may be supplying the same product without comparable notification. Finally, the purchaser acknowledgement statements are not required to be sent for pesticides which are registered in the United States, although such pesticides may be substantially restricted in the United States.

EPA believes that it should help to ensure that information sent to other countries under section 17 is not only received but is usable and useful to those countries. Thus, EPA supports the development of decision-making capabilities and regulatory infrastructures in importing countries for pesticides. In 1988 and 1989, EPA co-sponsored workshops which were conducted for the Asia/Pacific Region in Bangkok, Thailand and Manila, Philippines. EPA also provided resource persons for FAO sponsored national workshops in China and Belize, a Pacific Island workshop in Noumea, New Caledonia, an African regional workshop in Ghana and a food safety workshop in China. In January 1990, a workshop for Latin American regulatory officials is scheduled to be held in Santiago, Chile, as well as another African regional workshop in Niger, sponsored by the U.S. Agency for International Development (AID). EPA



has also cooperated with international organizations such as FAO, WHO, the Pan-American Health Organization, the Asian Development Bank, the World Bank and bilateral agencies such as the AID, and the German Technical Assistance Agency to provide this training and assistance.

EPA also provides expertise through representation to expert meetings and on official delegations to UNEP, FAO, and WHO. Agency personnel have been assigned to the WHO's International Programme on Chemical Safety and to FAO to help develop summary documents and guidelines on pesticides for use by developing countries in their regulatory programs. In addition, EPA supports efforts such as FAO's implementation of PIC by providing resources and expert guidance.

In some cases, EPA provides technical assistance by "loaning" technical personnel for on-site consultation. For instance, EPA has assisted in the development of an environmentally sound control strategy for the locust plague in Africa. Further, EPA has entered into agreements with AID and the Peace Corps to provide expertise in the evaluation of the environmental impact of pest control strategies, the disposal of pesticides, the development of guidelines for the procurement of pesticides, and other related projects. As with the educational programs undertaken by EPA, these projects enable countries to improve the protection of their citizens and environment while obtaining the benefits of pesticide use.

EPA also hosts numerous international visitors who are trained in a variety of areas; such as: regulatory development, data evaluation, decision methods and procedures for pesticide regulation.

**4. Obtaining information from other countries.** EPA considers information exchange among countries to be an efficient use of resources. In receiving information about regulatory actions taken by the United States, EPA hopes that other countries will use the information and benefit from our experiences. Similarly, the United States is very interested in receiving information about regulatory activities underway in other countries, to improve the comprehensiveness of its regulatory review. For example, the United States has regular meetings with Canada and the United Kingdom, known as the "tripartite discussions" for the purpose of exchanging information on current regulatory activities. The United States has found these discussions to be very useful. In the context of the Organization for Economic Cooperation

and Development, the United States participated in technical level meetings on tributyltins which were instrumental in the development of its testing protocol, since other member governments were further along in their regulation of these compounds.

In summary, within the context of its existing resources, EPA has initiated a technical assistance and information service program to help foreign countries, in particular developing countries, establish scientifically-based, comprehensive pesticide regulatory programs. Adequate regulatory programs are needed to ensure that pesticides are used safely and that pesticide residue levels in food do not reach harmful levels. EPA believes that establishing successful regulatory programs in other countries will minimize the number of violations occurring in imported food. In addition, by sharing technical and regulatory information with foreign governments, EPA hopes to facilitate the harmonization of international standards which would diminish existing trade barriers.

Authority: 7 U.S.C. 136a.

Dated: February 2, 1990.

Linda J. Fisher,

Assistant Administrator for Pesticides and Toxic Substances.

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## ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152, 153, 155, 156, 157, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173 and 180

[OPP-170000; FRL 3665-2]

### Statement of Policy on the Labeling Requirements for Pesticides, Devices, and Pesticide Active Ingredients Intended for Export and Procedures for Exporting Unregistered Pesticides: Proposal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed policy statement.

**SUMMARY:** In a policy statement issued on July 28, 1980, EPA explained in detail the requirements of section 17(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Specifically, the policy informed the public of the scope of the section 17(a)(1) labeling requirements, the procedures that exporters of unregistered pesticides must follow, and the unregistered products for which the exporter would

be required to comply with the purchaser acknowledgement statement requirement of section 17(a)(2).

EPA believes that changes are necessary to ensure compliance with the requirements of FIFRA regarding the use of pesticides and their effect on human health and the environment. Therefore, with this notice, EPA is proposing to clarify the labeling requirements for exported pesticides, devices, and pesticide active ingredients, and is proposing to amend EPA's policy regarding the procedures for exporting unregistered pesticides.

**DATES:** Comments must be received by EPA on or before May 14, 1990.

**ADDRESSES:** Submit written comments, identified by the document control number (OPP-170000), by mail to: Public Information Branch, Field Operations Division, Office of Pesticide Programs (H7506-C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Public Docket, 244 Bay, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. All written comments will be available for public inspection in the Public Docket at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** Stephen Howie, Office of Compliance Monitoring (EN-342), Rm. E-709B, 401 M St., SW., Washington, DC 20460, telephone (202) 382-7825.

**SUPPLEMENTARY INFORMATION:** Section 17(a) of FIFRA was amended in 1978, and after accepting public comment, EPA published a policy statement for section 17(a) in the Federal Register on July 28, 1980 (45 FR 50274). The 1980 policy statement explained what labeling is required to appear on exported pesticides, devices, and pesticide active ingredients, and what procedures an exporter of unregistered pesticides must follow to submit a statement from a foreign purchaser acknowledging that the purchaser is aware that the pesticide is unregistered for use in the United States and cannot be sold in the United States. EPA required a purchaser acknowledgement statement if the product: (a) Contained an active ingredient not found in a federally registered product; (b) bore labeling for a use which is currently subject to denial or cancellation of registration; or (c) was not similar in composition and use pattern to a federally registered product.

There has been increasing interest by foreign governments regarding the import of pesticides and their effect on human health and the environment in

their countries. There are currently efforts underway at the international level to assist governments in making informed decisions concerning pesticide use in their countries. EPA believes that the notification of foreign governments through the section 17(a)(2) submittal requirement of a purchaser acknowledgement statement is an important element in such decision-making by foreign governments. In addition, there is concern that pesticides which may have known or suspected adverse health effects, or which have not been tested at all, may be used on agricultural products which are then imported into the United States. There have been incidents where imported agricultural products tested for pesticide residues by the U.S. Department of Agriculture and the U.S. Food and Drug Administration were found to be contaminated with pesticides in excess of established legal limits, including pesticides which are banned for use in this country.

On April 25, 1989, the General Accounting Office (GAO) issued a report entitled "Pesticides: Export of Unregistered Pesticides is Not Adequately Monitored by EPA" (GAO/RCED89-128). This report identified several areas of concern regarding EPA's enforcement of the requirements of FIFRA section 17(a). Specifically, the GAO report identified problems in EPA's compliance monitoring program for FIFRA section 17(a), and suggested that the purchaser acknowledgement statement does not provide adequate transfer of useful information to both the importing country and EPA. In addition, GAO criticized the present policy's exemption from the section 17(a)(2) requirement of unregistered pesticides similar in composition and use to registered products because the exempt status of products is difficult to verify. Finally, GAO suggested that a number of pesticide exporters may not have been complying with the requirements of section 17(a).

The concerns presented in the GAO report were reiterated in a May 5, 1989 hearing before the House of Representatives Subcommittee on Environment, Energy, and Natural Resources, Committee on Government Operations, in which EPA was requested to reevaluate the current export policy program. In light of the issues raised by the Subcommittee, the GAO report, and the public, EPA conducted a comprehensive review of its pesticide export program, reevaluating the 1980 policy statement and its export enforcement programs. As part of this effort, EPA undertook an

inspection program during the summer of 1989 to evaluate compliance with the labeling requirements and submissions of acknowledgement statements. A preliminary review of the inspections conducted indicates a need for enhanced enforcement in this area and for the revisions in this proposed policy statement.

In addition, as a part of its comprehensive pesticide export policy review, EPA examined its policies and procedures concerning: (1) The notification of foreign governments of significant actions taken on pesticide registrations under FIFRA section 17(b); (2) compliance with prior informed consent (PIC) programs adopted through the United Nations; (3) cooperation in international efforts to improve pesticide research and regulations under FIFRA section 17(d); (4) providing technical assistance to countries importing pesticides and exporting food to the United States; and (5) confidential treatment of information concerning pesticide exports. EPA's review regarding these matters is discussed in the Proposed Pesticide Export Policy Statement published elsewhere in this issue of the Federal Register.

To ensure that there is a full understanding of the proposed policy statement for section 17(a), the policy presented in this document includes those portions which are being continued from the 1980 policy statement. The changes being proposed to the 1980 policy statement and the options under consideration, are explained in Unit I of this document. Explanations for the unchanged portions of the policy which are restated in Units III, IV and V of this document, may be found in the 1980 policy statement at 45 FR 50274 (July 28, 1980).

EPA is interested in receiving the comments from the public and other governments on the proposed policy presented in this document, particularly on the proposed changes in the policy involving the acknowledgement statement requirement. EPA seeks comment specifically on: (1) Whether removing the similar in composition and use exemption would significantly increase the number of exporters required to obtain the purchaser acknowledgement statement and thus increase respondent burden; (2) whether or not such notices would serve a useful purpose to importing countries; and (3) the alternative requirements presented, if the exemption were maintained.

Accordingly, EPA proposes the following policy with regard to the requirements for pesticides, devices, and

active ingredients used in producing pesticides intended solely for export.

#### I. Proposed Revisions to the 1980 Policy

Generally, FIFRA section 17(a) describes two requirements: section 17(a)(1) describes the requirements on the exported product, including labeling, and section 17(a)(2) describes the requirement for obtaining a foreign purchaser acknowledgement statement for the export of an unregistered pesticide. Section 17(a)(1) requires that pesticides, devices, and active ingredients used in producing pesticides which are intended solely for export comply with certain labeling provisions of FIFRA section 2, the establishment registration procedures and reporting requirements of section 7, as described in 40 CFR part 167, and the inspection and recordkeeping requirements of section 8, as described in the statute and 40 CFR part 169.

##### A. Applicability

The most important modification EPA is considering relates to the administrative exemption to section 17(a)(2) provided in the 1980 policy statement for exported unregistered pesticides that are substantially similar in composition and use to registered pesticides. EPA is considering either: eliminating the exemption entirely, requiring any person who exports an unregistered pesticide to obtain a purchaser acknowledgement statement and submit it to EPA; or maintaining the exemption, but requiring exporters to substantiate claims that exported products are substantially similar in records maintained and made available to EPA, or its representative, upon request, or in reports submitted directly to EPA.

In addition, although EPA addressed the applicability of section 17(a) to research products in the discussion of comments section of its 1980 policy statement, EPA believes that the policy regarding such products should be clarified. EPA is proposing that, for the purposes of this policy, section 17(a)(2) not apply to research products, and will provide specific guidance as to what is and is not considered to be a research product. EPA believes that such products should not require purchaser acknowledgement statements when they are exported for the sole purpose of determining their pesticidal value, toxicity, or other characteristics, and when there is no expected pesticidal benefit to be derived from use of the material. To provide adequate safeguards against the use of research products in a way that could cause risk

to human health and the environment. EPA proposes further clarifying its position regarding what qualifies as a research use. EPA considered proposing that qualification as research use be determined by the quantity of product shipped, but believes that it is difficult to define a set amount that would define research use for all products. Consequently, EPA is proposing that the presumption of research use be based on the actual intended use of the product. Therefore, EPA proposes that a research use will not be presumed if tests of the product are: (1) Land uses of more than 10 acres, or which affect food or feed crops which are intended for consumption; (2) aquatic uses of more than 1 acre, or which involve water used for irrigation, drinking, or recreation, or which affect plants or animals taken for food or feed from such waters; or (3) tests on or with animals which may subsequently be used for food or feed. EPA further proposes that the exporter bear the burden of demonstrating that the product qualifies for the research exemption, before the research product is shipped, since it is not possible for EPA to directly monitor research uses once the product is exported. The range of options for demonstrating that a product is for research use only include requiring exporters to maintain records for 3 years after the export supporting the research claim, or to submit a statement identifying the shipment and stating that the product is being shipped as a research product as defined by the guidance provided in this document.

#### *B. Labeling*

The proposed policy statement would clarify EPA's position that all unregistered products, including ones that are similar in composition and use to registered products, must comply with the labeling provisions of section 17(a)(1), and that all products not bearing a valid EPA registration number must contain the following language on their label or labeling: "Not Registered for Use in the United States of America." EPA believes that section 17(a)(1), together with section 2(q)(1)(H), requires all unregistered products exported from the United States to be labeled as such. To comply with the statute, this label statement must appear on the products. Thus, for the purpose of the section 17(a)(1) labeling requirements, a pesticide which is not registered for use under section 3 will be considered to be unregistered and therefore must bear the bilingual statement "Not Registered for Use in the United States of America."

If the similarity in composition and use exemption for unregistered

pesticides is maintained with regard to the requirement to submit purchaser acknowledgement statements, EPA proposes requiring the ingredient statement to be as consistent as possible with existing rules regarding the labeling of registered pesticides, in accordance with section 17(a)(1). As such, EPA seeks to avoid any ambiguity regarding what are accepted as the common and/or chemical name of the product in the United States. Where different common and/or chemical names apply in the importing country, EPA's requirement may be met through the use of supplemental labeling as described in this policy.

The proposed policy would also clarify that all exported pesticides are subject to the provisions of FIFRA sections 2(p) and 2(q), as specified in section 17(a)(1) and described in detail in this document. However, in the case that doing so conflicts with requirements of the importing country, EPA would still permit the use of supplemental labeling to meet the EPA requirements and to accommodate the labeling requirements of importing countries.

Although this policy statement proposes to continue requiring certain labeling statements to be bilingual, EPA is soliciting comments on requiring that the labeling statements which are currently required to be bilingual, be multilingual. As such, the previously bilingual labeling requirements would be required to be in English, in the language of the purchaser's country, and, if different, in the language of the country of final destination.

#### *C. Purchaser Acknowledgement Statement*

EPA proposes modifying its policy regarding exemptions from the purchaser acknowledgement statement requirement of section 17(a)(2) for unregistered pesticides similar in composition and use to registered pesticides. EPA intends to reiterate that purchaser acknowledgement statements are to be obtained from the foreign purchaser, but, to improve the utility of these statements, EPA is proposing that the statements be applicable to countries of purchase and of final destination, and is proposing that the statements be required to be multilingual. As such, the statement would be required to be in English, in the language of the foreign purchaser's country, and, if different, in the language of the final destination. EPA is also proposing that, in the case where more than one language is involved due to more than one destination, e.g., where an intermediary ships to multiple

countries of final destination, either a multilingual statement be submitted to EPA, or multiple statements in all required languages be submitted to EPA.

Finally, EPA is soliciting comments on the option of requiring reporting for each shipment, rather than annually for the first shipment by a particular exporter to a particular purchaser for each importing country.

1. *Similar in composition and use exemption.* In the 1980 policy statement, EPA stated that exported pesticide products that are claimed to be similar in composition and use to registered pesticides were exempt from the provisions of section 17(a)(2). Such similarity was defined in the 1980 statement as claimable if the product had the same active ingredients, the same use pattern, and the same general toxicity as a registered pesticide. However, EPA has since determined that there are difficulties in confirming the validity of such similarity claims. In practice, the 1980 policy places on EPA the burden of evaluating each similarity claim for which no acknowledgement statement was submitted to determine whether the exported product is indeed similar to a registered product. Such an interpretation makes it difficult to ascertain whether such claims are valid during an inspection, and requires a high use of resources to effectively enforce the acknowledgement statement requirement. EPA has determined that there are basically two alternatives that would resolve this issue: either remove the exemption, or require exporters to support any exemption claimed.

EPA is considering both options in this proposal. EPA encourages comments on this issue, particularly regarding the records and reports that would be required, and the utility to the importing country's government, if EPA were to maintain the exemption for unregistered products similar in composition and use to registered products. The two options are:

a. *Removal of the exemption.* EPA could remove the similar in composition and use exemption entirely. By removing the exemption, all unregistered pesticides, regardless of similarity in composition and use to registered pesticides, would be subject to the acknowledgement statement requirements of section 17(a)(2). In removing the exemption, EPA would require the exporter to obtain and submit to EPA purchaser acknowledgement statements for all exported unregistered pesticides in accordance with the procedures outlined in Unit V of this document. EPA specifically solicits comments regarding

the impact on both industry and the governments of receiving countries in terms of the number of notices that may be required if this exemption is removed, and any potential benefit to importing countries. EPA estimates that four times as many purchaser acknowledgement statements may result under this option.

*b. Retain the exemption.*

Alternatively, EPA could retain the similar in composition and use exemption, and require additional verification on the part of the exporter to substantiate any exemption claimed. EPA believes that the existing exemption, by reducing the number of acknowledgement statements transmitted, increases the utility and importance given to statements involving unregistered products which have been judged to be hazardous or for which no assessment has been made. However, EPA believes that it is acceptable to exempt such products only if there is no question concerning the validity of the claim. Hence, any exported unregistered product that is substantially similar in composition and use to a registered product, as specified in the 1980 policy and as reiterated in this policy, would not require a purchaser acknowledgement statement if appropriate recordkeeping requirements and/or reporting to support the claim are met.

In proposing this option, EPA believes that verification of claims will not require substantial effort on the part of exporters, since the decision to claim such an exemption should be based upon existing documentation. This option requires that such documentation be made available to EPA upon request, and will be expected to be maintained for 3 years after the date of export. If the exemption is retained, EPA will consider requiring the retention of certain records in addition to requiring the submission of reports in support of the similarity claims. EPA encourages comment on the incremental benefits and burdens of requiring reporting in addition to maintaining records of similarity claims. Reports or records would identify that such claims are made and the basis for the claim, i.e., the registered product's identity and the characteristics that establish sufficient similarity between the registered product and the unregistered product. The basic criteria for an exemption, as explained in the 1980 policy, will remain the same.

*2. Multilingual purchaser acknowledgement statements.* EPA proposes that purchaser acknowledgement statements be multilingual, in English and in the

language of the country where the foreign purchaser is located, and, if different, in the language of the country of final destination. EPA believes that it is important for the purchaser acknowledgement statements to be understood by the officials of the governments to whom they are transmitted, as well as by the persons who sign them. In cases where more than one language would be needed, e.g., where a pesticide product is shipped to a purchaser who repackages or reformulates for shipment to a number of other countries, EPA is proposing to allow multilingual statements, or to require multiple statements. EPA is interested in receiving comments on this language requirement.

*3. Country of final destination.* EPA would consider products not labeled appropriately for the country of intended final destination (i.e., the country of intended use), and purchaser acknowledgement statements that do not include the country of final destination or which do not meet the multilingual requirements, to not meet the requirements of section 17(a). EPA believes that it was the intent of Congress to provide through section 17(a) assurance that: (1) Exported pesticide products be labeled in a manner to help assure safe use; and (2) importing governments be sufficiently aware of the import of an unregistered U.S. product into their countries, so as to enable them to identify potential risks. These purposes can best be served if the provisions of this section are directed toward the country of intended use. EPA intends to send copies of the purchaser acknowledgement statement to the government of the country where the foreign purchaser is located and of each country of final destination.

## II. Requirements of FIFRA Section 17(a)

FIFRA section 17(a) states that producers of pesticides, devices, and active ingredients used in producing pesticides which are intended solely for export are subject to the requirements of FIFRA sections 2(p) (labeling), 2(q)(1) (A), (C), (D), (E), (G), and (H) and 2(q)(2) (A), (B), (C) (i) and (iii) and (D) (misbranding), section 7 (establishment registration) and section 8 (inspections and books and records). In addition, unless a pesticide is registered under section 3 or is being sold under section 6(a)(1), it cannot be lawfully exported unless, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that the pesticide is not registered for use in the United States and therefore cannot be sold in the

United States. A copy of this statement is required to be transmitted to an appropriate official of the government of the importing country.

## III. Applicability

For the purposes of the section 17(a) policy, a pesticide product which has been registered under section 24(c) of FIFRA will be considered registered, while a pesticide product which may be legally used only under an experimental use permit (section 5) or an emergency exemption (section 18) will be considered to be unregistered. In addition, a pesticide product whose sale and distribution are legal in intrastate commerce because the producer has filed an application for Federal registration in accordance with the procedure found in 40 CFR 152.230, will be considered to be unregistered for the purposes of this policy. Further, technical grade and manufacturing use pesticides which are not federally registered will be considered to be unregistered for the purposes of this policy.

Pesticide products exported solely for research purposes will be exempted from the purchaser acknowledgement statement requirement of section 17(a)(2). Such research use occurs when the purpose of the shipment is only to determine its value for pesticide purposes or to determine toxicity or other properties, and when the user does not expect to receive any benefit in pest control from its use. Research use will not be presumed if tests are: (1) Land uses of more than 10 acres, or which involve or affect food or feed crops intended for consumption; (2) aquatic uses of more than 1 acre, or which involve water used for irrigation, drinking, or recreation, or which affect fish, shellfish, or other plants or animals taken for food or feed from such waters; or (3) tests on or with animals which may subsequently be used for food or feed.

EPA proposes that the exporter bears the burden of demonstrating that the pesticide qualifies for the research exemption, and must document it before the research product is shipped, since it is not possible for EPA to directly monitor research uses once the product is exported. Exporters shall maintain records for 3 years after the export supporting the research claim. These records would, at a minimum, include verification from the foreign purchaser indicating that the product was used for research in accordance with the guidance provided in this document. EPA is also considering requiring exporters to submit a statement

identifying the shipment and stating that the product is being shipped as a research product as defined by the guidance provided in this document. EPA is soliciting comments on this proposal regarding the applicability of section 17(a) to research products.

Finally, all products, research or otherwise, transferred from a domestic facility to a foreign facility of the same company will be required to comply with the section 17(a) requirements and will be treated in accordance with their U.S. registration status, i.e., a U.S. registered product must comply with the labeling requirements of section 17(a)(1), while an unregistered product must comply with both the label requirements of section 17(a)(1) and (except in the case of research products as specified above, or in the case where the product is similar to a registered product, should the "similar in composition and use" exemption be retained) the purchaser acknowledgement statement requirement of section 17(a)(2). Failure to comply with the requirements of section 17(a), or to maintain records for 3 years after the export, or to allow EPA access to such records as requested, is a violation of FIFRA section 12 and may result in civil or criminal penalties.

#### IV. Label and Labeling Requirements

Every exported pesticide, device, and active ingredient used in producing a pesticide must bear a label or labeling which meets the requirements of FIFRA section 17(a)(1). In addition, certain information which will satisfy FIFRA section 2(q)(1) (E), (G), and (H) and 2(q)(2) (A) and (D) must appear bilingually on the label or labeling, in English and in the language of the country of intended final use. This information is intended to provide important information to anyone who handles or comes in contact with these products. Therefore, to be considered in compliance with this requirement, the exporter must use the language in which official government business is conducted in the country of final destination, or other language required by such country. When there are several official dialects in the country, that language which is predominately spoken will be acceptable. Further, since labeling is also intended to provide information to all persons coming in contact with the product, EPA is also requesting comments on its proposal that the label or labeling be multilingual, i.e., in English, in the language of the purchaser's country, and, if applicable, in the language of the country of final destination. Should that proposal be adopted, the term multilingual would

replace the term bilingual throughout this unit.

#### A. General Requirements

Pursuant to section 17(a)(1), all exported pesticides, devices, and active ingredients used in producing pesticides must bear a conspicuous and readable label or labeling which includes:

1. EPA establishment numbers.
2. Ingredient statements.
3. Name and address of the producer, registrant (if any), and the name of the person for which the product is produced.
4. Net weight or measure.
5. Skull and crossbones, if the pesticide is highly toxic, and statements of practical treatment in case of poisoning.
6. Warning and caution statements.
7. The statement "Not Registered for Use in the United States of America," if the pesticide is not registered for the particular use for which it is being exported.

Moreover, the label or labeling shall not make false representations or be in imitation of other products.

FIFRA section 2(q)(1)(E) specifies that required statements must be represented " . . . in such terms as to render it likely to be read and understood by the ordinary individual . . . ". Therefore, to satisfy this section the following information must appear bilingually, in the English language and in the language of the country of final destination, on all exported product labeling:

- a. The warning and caution statements.
- b. The ingredient statement.
- c. Where required, the word "Poison" and the statement of practical treatment in case of poisoning.
- d. The statement "Not Registered for Use in the United States of America."

#### B. Specific Guidance

The following provides more specific guidance on particular elements which must appear on the label or labeling of each exported product:

1. *EPA establishment number.* The establishment number may appear anywhere on the label or immediate container in accordance with the establishment registration labeling requirements set forth in 40 CFR 156.10(f).
2. *Precautionary statements.* Warning or caution statements must be bilingual and must be adequate for the protection of persons handling the pesticide, particularly with respect to general toxicological hazards and environmental, physical, or chemical hazards. Where the bilingual translation

is obviously inappropriate to protect residents of the importing country, (for example, where a label calls for a gas mask meeting the specification of the U.S. Bureau of Mines) an equivalent caution must be substituted.

3. *Unregistered products.* The labels of all pesticides which are not registered for a particular use or uses in the United States under FIFRA section 3, must prominently display the following statement bilingually: "Not Registered for Use in the United States of America." Unregistered pesticides must also comply with all other labeling provisions under section 17(a)(1). In addition, unregistered pesticides claimed to be similar in composition and use to registered pesticides, if the exemption is retained, must bear cautionary and ingredients statements that are similar to those approved by EPA for registered pesticides posing comparable hazards.

4. *Ingredient statement.* The ingredient statement must appear bilingually on the labeling, unless the ingredients are easily identifiable and likely to be understood by the ordinary individual, despite their being listed in a foreign language. If the "similar in composition and use" exemption is retained and is claimed, the ingredient statement for the unregistered product must be similar to that of the registered product, e.g., uses same chemical or common name for active ingredients.

5. *Use classification statement.* The statement of use classification (Restricted Use Pesticide or General Use Pesticide) must appear on the labeling of the pesticide; however, summary statements regarding the terms of the restriction, e.g., "For retail sale to and application only by Certified Applicators . . . " are not required.

6. *Identity of parties.* Name and address of the producer, registrant (if any), and the person for whom the pesticide was produced, must appear in the labeling.

7. *Net weight.* The net weight must appear on the labeling in conventional English units and metric units.

8. *Highly toxic pesticides.* If the pesticide is highly toxic, the skull and crossbones, the word "Poison", and a statement of practical treatment must appear on the labeling. The word "Poison" and the statement of practical treatment shall be bilingual. The skull and crossbones may be in red or black. For guidance on what pesticides are highly toxic, see 40 CFR 156.10(h).

#### C. Supplementary Labeling

All exported pesticides must comply with the labeling requirements of FIFRA

sections 2(p) and 2(q), as specified by section 17(a)(1) and as described in this policy statement. However, EPA is concerned that these labeling requirements not conflict with the labeling requirements of the country of intended use. To avoid conflicts, yet still meet the statutory requirements of FIFRA, exporters may use supplemental labeling to meet the requirements of FIFRA. Therefore, exported pesticides, devices, and active ingredients used in producing pesticides which are intended solely for export must bear a label with the appropriate information required by FIFRA, or, in instances where FIFRA required labeling is in direct contravention of foreign labeling requirements, may be accompanied by supplemental labeling which meets those requirements of FIFRA that conflict with the requirements of the importing country. All information required by FIFRA and not directly conflicting with the laws of the country of intended use, must appear on the label affixed to the product container. Any supplemental labeling, which is permitted when FIFRA required labeling contravenes foreign labeling requirements, must be attached to or accompany the product container or shipping container to the final destination. It is EPA's position that the exporter bears the burden of proving that the foreign laws conflict with FIFRA. Accordingly, the exporter must be prepared to substantiate any claim that foreign labeling requirements preclude the label information required by FIFRA from being placed directly on the product container.

#### V. Purchaser Acknowledgement Statement Requirement

FIFRA section 17(a)(2) states that any pesticides other than a pesticide registered for use under section 3 or sold under section 6(a)(1) shall have a purchaser acknowledgement statement signed by the foreign purchaser prior to export, acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States. A copy of the statement is required to be transmitted to an appropriate official of the importing country.

EPA will continue to require that the exporter obtain the purchaser acknowledgement statement on an annual basis for the first shipment of each unregistered pesticide to a particular purchaser for each country of final destination. The statement must be submitted to EPA, along with a certification signed by the exporter that the statement was obtained prior to the

release of the product for shipment. The statement and certification must be transmitted to EPA within 7 days of receipt by the exporter, or by the date of export, whichever comes first. The statement will be transmitted by EPA to the appropriate officials of the importing country. EPA is considering, as an option, requiring reporting for each shipment and is soliciting comments on this issue.

#### A. Products Subject to the Requirement

As stated in the 1980 policy, the requirement for obtaining an acknowledgement statement from a foreign purchaser will apply to pesticide products where:

1. The pesticide active ingredient has been judged to pose "unreasonable adverse effects" to human health or the environment, and the registrations of products with that active ingredient have been cancelled, denied, or voluntarily withdrawn for health and safety reasons; or
2. Either, (a) no assessment or no conclusive assessment of the hazard resulting from the use of the pesticide has been made by EPA (while the pesticide may have been used under limited experimental or emergency conditions), or (b) the pesticide has never been registered under section 3 because registration for the pesticide active ingredient has not been sought or has not yet been granted.

In addition to those situations expressly noted in the 1980 policy statement, EPA interprets section 17(a)(2) as applying to all pesticide products which: contain an active ingredient that is not found in an EPA registered product; or, bear labeling for a use which is currently subject to denial or cancellation of registration, including uses not considered by the Administrator during a cancellation or denial determination and those uses voluntarily withdrawn due to health concerns.

In the 1980 policy statement, EPA also included the statement that the requirement would apply to pesticide products in which "the pesticide is being exported for a use which is substantially different from any currently registered use of that pesticide (e.g., a pesticide which is registered in this country for use as a termiticide is exported for use on food crops)." Therefore, unregistered pesticides which are not, as determined by EPA, substantially different from registered products were considered to be exempt from the purchaser acknowledgement statement requirement. This was based on EPA's belief that Congress did not intend the requirement to obtain a purchaser

acknowledgement statement to apply to pesticide products which are minor variations on formulations registered in the United States and which contain only active ingredients which are registered in the United States. EPA used its enforcement discretion to allow for the export of unregistered pesticide products with minor variations from registered pesticides, without requiring purchaser acknowledgement statements to be obtained and submitted to EPA. Recently, EPA has determined that the exemption renders compliance monitoring of the purchaser acknowledgement statement requirements problematic, since it is difficult to verify whether a product claimed to be exempt is similar to a registered product.

In this document EPA is presenting the following two options concerning products subject to the purchaser acknowledgement statement requirement. Although only two basic options are being proposed, EPA is considering and is interested in receiving comments on the array of alternatives available between these options. After reviewing public comments, EPA will adopt one of the options in its final policy statement.

(1) Option 1. *Require acknowledgement statements of all unregistered products.* All exported pesticide products are required to comply with the labeling provisions of section 17(a)(1) as specified in Unit IV of this document, and, pursuant to section 2(q)(1)(H), all unregistered pesticide products shall also bear the following bilingual label statement: "Not Registered for Use in the United States of America." In addition, all exporters of unregistered pesticide products must obtain and submit to EPA a purchaser acknowledgement statement as required by section 17(a)(2).

Unregistered pesticides which are produced in the United States solely for export may contain active ingredients that are also registered as components of pesticides used in the United States. However, such products are still considered to be unregistered, and as such must comply with the purchaser acknowledgement statement requirement as described in this policy.

(2) Option 2. *Retain the exemption with provisions to improve verification of validity of exemption claims.* Some pesticides produced in the United States which are intended solely for export contain active ingredients that are also components of registered pesticides used in the United States. In some cases, the export formulations may contain slightly different percentages of active



ingredients and may be labeled differently and are therefore "unregistered" within the meaning of section 3. Rather than require formal registration, certain unregistered pesticides, as determined by EPA, which are similar in composition and use to, or which contain the same active ingredient as, an EPA registered product, shall be considered exempt from the purchaser acknowledgement statement requirement of section 17(a)(2). EPA is concerned that requiring acknowledgement statements for such pesticides is not necessarily useful to the governments of importing countries, and could detract from the attention drawn to more significant notices regarding pesticides which have been banned, restricted, or otherwise denied use for health or safety reasons, or which are unassessed.

Exporters of all unregistered pesticide products that are not, as determined by EPA, similar in composition and use pattern to an EPA registered product must comply with section 17(a)(2). To be considered similar in composition and use pattern, a pesticide product must contain only the same active ingredient or combination of active ingredients, must have the same category of toxicity (i.e., same signal word), and must have a similar use pattern as an EPA registered product.

Products involving changes in use patterns such as changes from non-food to food use, outdoor to indoor use, terrestrial to aquatic use, or non-domestic to domestic use, are not considered to qualify as similar use patterns. Pesticide uses which were never reviewed during a cancellation or denial of registration determination (such as a pesticide use on a crop which is not grown in the United States), or uses which have been voluntarily withdrawn, will not qualify as a similar use, and therefore require an acknowledgement statement.

In addition, if an exporter claims that the unregistered pesticide product it is exporting is similar in composition and use pattern to an EPA registered pesticide, and therefore exempt from the purchaser acknowledgement statement requirement, the exporter shall bear the burden of proving the validity of such a claim. To ensure that such claims are valid, EPA is considering the options that: (a) Records be kept for a minimum of 3 years following exportation, supporting each claim; and/or (b) all claims for exemptions be supported by a report to EPA, submitted prior to the first shipment in a given year, demonstrating the validity of the claim.

Therefore, if EPA retains the exemption, an exporter of an

unregistered product claiming this exemption must either maintain records for 3 years after the export or submit a report to EPA documenting such a claim. This documentation shall include:

- a. Records already required under section 8.
- b. Copies of labeling information from the registered product.
- c. Documentation affirming the similarity of composition and use between the unregistered product and the registered product used to support the similarity claim. EPA is considering requiring that records documenting the similarity claim be maintained by the exporter pursuant to section 8, and that the records be made available to EPA upon request. In addition, EPA is alternatively considering requiring the exporter to maintain the data supporting the similarity claim, or requiring reports to be submitted prior to the export of the pesticide for which the similarity claim is made. If EPA determines that the claim of similarity for a particular product is without merit, EPA will consider all exports of the pesticide without a purchaser acknowledgement statement to have been in violation of FIFRA.

Furthermore, pursuant to section 2(q)(1)(H), all unregistered pesticide products, including those which are similar in composition and use pattern to an EPA registered product, must bear the following bilingual label statement: "Not Registered for Use in the United States of America." This is consistent with EPA's interpretation that all exported pesticide products must comply with the labeling requirements of section 17(a)(1) as detailed in Unit IV of this document.

#### *B. Procedures for Obtaining and Transmitting Purchaser Acknowledgement Statements*

The procedure that an exporter of unregistered pesticides must follow in obtaining and transmitting the foreign purchaser acknowledgement statements are as follows:

1. The exporter must provide the foreign purchaser with instructions about the required information on a purchaser acknowledgement statement and inform the foreign purchaser that the shipment of the pesticide product cannot be undertaken unless the exporter has received from the foreign purchaser a properly completed, signed, and dated acknowledgement statement.
2. The exporter must secure, prior to shipment, a purchaser acknowledgement statement which contains the information outlined in the Required Information section of this document. Such a statement must be multilingual

and must be secured for the first purchase each year of a particular pesticide product by the foreign purchaser destined for each particular country. If a foreign purchaser makes subsequent purchases from the exporter that are intended for different destination countries than those identified in any acknowledgement statements provided earlier in that year, purchaser acknowledgement statements must be obtained before shipment of those subsequent purchases to the foreign purchaser can be made. Foreign purchasers may provide a single acknowledgement statement in the languages of all countries of intended destination that identifies all the countries of intended destination before the first purchase in a year, or foreign purchasers may provide separate acknowledgement statements for each country of ultimate destination at the beginning of the year or at the time of the purchases that are intended for those destinations.

3. The purchaser acknowledgement statement, along with the certification signed by the exporter that exportation did not take place until a signed acknowledgement statement was received, must be submitted to EPA within 7 days of receipt by the exporter, or by the date of export, whichever occurs first. The purchaser acknowledgement statement must be transmitted to the following address: Environmental Protection Agency, Office of Compliance Monitoring (EN-342), 401 M St., SW., Washington, DC 20460, Attention: Export Acknowledgement Statement.

4. If EPA retains the "similar in composition and use" exemption for unregistered products, as discussed in Option 2 of this unit, and an exporter claims the exemption, the exporter must maintain the appropriate records necessary for verifying the claim, and may also be required to submit appropriate verification of the claim.

In addition, if EPA allows a "research" exemption as discussed in this document, and an exporter claims the exemption, the exporter must maintain records for 3 years after the export supporting the research claim and, if adopted, submit to EPA the appropriate statement verifying the claim.

5. Currently, after the exporter obtains and submits to EPA the signed foreign purchaser acknowledgement statement, EPA transmits a copy of the statement to the State Department, which in turn transfers it to an appropriate government official in the importing country. EPA is considering amending

this procedure to provide direct transmittal from EPA to the appropriate government official in the receiving countries. EPA believes that this will expedite the transfer of information which may be essential for informed decision-making by potential receiving countries.

### C. Information Required in the Purchaser Acknowledgement Statement

The purchaser acknowledgement statement must include the following multilingual information, in English, in the language of the purchaser's country, and in the language of the country of final destination, if different:

1. Name and address of the exporter.
2. Name and address of the foreign purchaser.
3. Name of the product and the active ingredient.
4. Statement that indicates that the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States.
5. Country or countries of final destination of the export shipment, i.e., where the exported pesticide is intended to be used, if different from the foreign purchaser's address.
6. Signature of the foreign purchaser.
7. Date of the foreign purchaser's signature.

Although EPA does not currently require a particular format for the statement, EPA solicits comments on whether the statement would be of more utility if a specific format was required, or a particular form provided, e.g., a form similar to and in harmony with the accepted international form for notification under the PIC program.

### VI. Confidentiality

Persons submitting the information specified in the purchaser acknowledgement statement may assert a claim of business confidentiality by marking the information claimed confidential as "FIFRA Confidential Business Information." Information so claimed will not be disclosed, with the exception of disclosure to the foreign government, except in accordance with the procedures set forth in 40 CFR part 2, 7 U.S.C. 136h, and this policy statement. If such a claim is not asserted, EPA may disclose the information to the public without providing further notice prior to disclosure or an opportunity to object. Notwithstanding any claim of confidentiality, the purchaser acknowledgement statement will be forwarded to the appropriate foreign government officials in its entirety, as required by section 17(a)(2).

In addition, the following information will generally not be considered confidential since it is considered to be a part of information in the public record: (a) The fact that a producer makes a registered or unregistered pesticide product; (b) the fact that an acknowledgement statement or other notice of export has been filed by an exporter; and (c) the name of the exported product, and, if applicable, the names of the active ingredients of the pesticide. Therefore, the information listed in the Required Information section under Unit V.A.1 and 3 of this Notice will not be entitled to confidentiality.

EPA believes that other information, such as the name of the country of final destination and quantity of export, may not be entitled to confidential treatment, and is reviewing the confidential status of that information. EPA will include, in its final policy statement, a statement of its findings regarding the confidentiality of such information.

### VII. Relationship to Other Statutory Requirements

Producers of any pesticide, device, or active ingredient used in producing a pesticide which are intended for export are subject to the requirement to register the establishment in which the pesticide is produced, including the reporting requirements of FIFRA section 7 and the regulations at 40 CFR part 167, as well as the recordkeeping requirements of FIFRA section 8 and the regulations found at 40 CFR part 169.

EPA does not consider it a violation of FIFRA to produce a pesticide, device, or pesticide active ingredient for export in accordance with the directions of a foreign purchaser, when properly labeled and, in the case of unregistered pesticides, when the foreign purchaser has signed the required purchaser acknowledgement statement and the exporter has forwarded this statement to EPA.

Exported pesticides, devices, and active ingredients used in producing pesticides which do not bear labels or labeling in compliance with FIFRA section 17(a)(1) will be considered to be misbranded. Exporters of such pesticides or devices will be subject to civil or criminal liabilities for violation of FIFRA section 12(a)(1) (E) or (F)—misbranding. Exporters of unregistered pesticides who fail to secure the required purchaser acknowledgement statement will be subject to civil or criminal liabilities for violation of FIFRA section 12(a)(1)(A)—selling or distributing an unregistered pesticide, or section 12(a)(2)(M)—falsifying information submitted to EPA or records

required to be maintained. Falsification of the required certification may subject an exporter to sanctions under 18 U.S.C. 1001.

### VII. Other Regulatory Requirements

#### A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether an action is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that the proposed revisions do not constitute a major action because they do not meet any of the criteria set forth and defined in section 1(b) of the Order. Costs were estimated based on existing program experience, including the number of annual submissions presently made to EPA that would be affected by proposed changes.

This policy was submitted to OMB for review as required by Executive Order 12291. Any comments from OMB to EPA and any EPA response to those comments are available for public inspection in the public file at the Public Docket location listed under the ADDRESSES section of this document.

#### B. Paperwork Reduction Act

This policy proposes to amend provisions of the foreign purchaser acknowledgement statement of unregistered pesticides program which are currently cleared by the Office of Management and Budget (OMB) under control number 2070-0027. The information collection requirements imposed by this proposed policy statement have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. A copy of the information collection request (ICR) document may be obtained from the Information Policy Branch of the Office of Policy, Planning and Evaluation (OPPE) of EPA at the address given below.

Public reporting for this collection of information is estimated at an average of 0.75 hours per acknowledgement statement, with an additional 0.25 hours to fulfill the multilingual requirement and an alternate 0.50 hours for those claiming the research exemption. An estimated 976 acknowledgement statements and an estimated 195 research claims per year will be required under this activity, for a total of 1074 hours of annual burden. This adds 891 hours to the estimated annual burden of this activity, which, under the existing program is estimated to consist of a total annual burden of 183 hours, based on an average of 0.75 hours per acknowledgement statement and 244



statements per year. This includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this

collection of information to: Chief, Information Policy Branch (PM-233), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, and to the Office of Management and Budget (Paperwork Reduction Project; 2070-0027), Washington, DC 20503, Attention: Desk Officer for EPA.

Authority: 7 U.S.C. 136o.

Dated: February 2, 1990.

Linda J. Fisher,

Assistant Administrator for Pesticides and Toxic Substances.

[FR Doc. 90-3250 Filed 2-8-90; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 168 and 169

[OPP-170003; FRL 4000-1]

RIN 2070-AC09

### Pesticide Export Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Policy Statement.

**SUMMARY:** This document sets forth the final version of EPA's revised pesticide export policy. This policy replaces EPA's existing pesticide export policies, which were published in the Federal Register on May 14, 1975 and on July 28, 1980. This policy eliminates an exemption provided in the 1980 policy from the requirement to obtain a purchaser acknowledgement statement, clarifies the requirements for labeling exported pesticides, and clarifies the requirements affecting the export of research and development pesticides. EPA believes that these changes and clarifications will increase the usefulness of information on exported U.S. pesticides sent to other countries, and simplify compliance with the export requirements. The policy also discusses whether certain information about unregistered pesticides submitted to EPA will be considered confidential. Changes to EPA's program to notify countries of U.S. pesticide regulatory actions are discussed. EPA is broadening the scope of actions which will trigger international notifications, and is prioritizing the timing of transmitting these notices to other governments. The policy also presents a new system for transmittal of international notices, whereby EPA will be transmitting advance copies of the notices directly to countries and the State Department will notify the appropriate embassies. **EFFECTIVE DATE:** This policy is effective [insert date 60 days after date of publication in the Federal Register], except for § 168.75 which will be effective June 1, 1993.

**FOR FURTHER INFORMATION CONTACT:** For information about the FIFRA section 17(a) requirements regarding labeling of pesticides intended for export and procedures for exporting unregistered pesticides contact: Stephen Howie, Office of Compliance Monitoring (EN-342W), U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C., 20460 U.S.A.; telephone (703) 308-8290; facsimile (703) 308-8218.

For further information about FIFRA section 17(b) notification programs or EPA's international pesticide activities contact: Deborah Hartman, Office of Pesticide Programs (H-7501C), U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C., 20460 U.S.A.; telephone (703) 305-7102; facsimile (703) 305-6244.

#### SUPPLEMENTARY INFORMATION:

**Electronic Availability:** This document is available as an electronic file on *The Federal Bulletin Board* at 9:00 a.m. on the date of publication in the Federal Register. By modem dial (202) 512-1387 or call (202) 512-1530 for disks or paper copies. This file is also available in Postscript, Wordperfect and ASCII.

The contents of this policy are listed in the following outline:

- I. Summary
- II. Background
  - A. Statement of EPA's Goals for International Pesticide Activities
  - B. Legal Authority
  - C. Global Pesticide Market; Exports from the United States; Pesticide Usage; Agricultural Imports
  - D. Reasons for Review of EPA's 1980 Policy Statement
- III. Discussion of the 1980 Policy, the 1990 Proposal, Public Comments, and Responses to Comments
  - A. 17(a)(1)-Label and Labeling Requirements for Exported Pesticides
  - B. FIFRA Section 17(a)(2)-Procedures for Exporting Unregistered Pesticides--Purchaser Acknowledgement Statement
  - C. Confidentiality
  - D. FIFRA Section 17(b) Notification Programs
  - E. Section 17(d) Activities
- IV. Technical Amendment
- V. Public Record
- VI. Other Regulatory Requirements
  - A. Executive Order 12991
  - B. Regulatory Flexibility Act
  - C. Paperwork Reduction Act
- VII. Export Policy and Procedures for Exporting Unregistered Pesticides

#### I. Summary

This policy discusses the requirement to obtain a purchaser acknowledgement statement for exporters of unregistered pesticides. This policy also allows certain unregistered pesticides to be exported for research and development (R&D) purposes without meeting the purchaser acknowledgement statement requirement, if the use in the country of import does not exceed the limits specified in criteria provided in this policy. Exporters are required to maintain records to substantiate claims that their products fit the exemption for R&D products.

EPA is also clarifying certain labeling requirements. Certain label statements which in the past had to be bilingual, may now be required to be multilingual, if applicable. The policy clarifies that all unregistered pesticides must have labels/labeling with the statement "Not Registered for Use in the United States of America." The policy also clarifies that research and development pesticide products must meet the labeling requirements of section 17(a)(1). The policy allows exporters to add explanatory language to use classification statements to explain the restricted status of the product.

The policy sets new procedures that exporters must follow to obtain and transmit

purchaser acknowledgement statements. The final policy requires per-shipment purchaser acknowledgement statements, but also provides an alternative means for satisfying this statutory requirement. More information is required in the purchaser acknowledgement statements, and the policy also discusses new procedures for the transmittal of purchaser acknowledgement statements.

EPA's notifications to other countries about pesticide regulatory actions are discussed. The policy provides that EPA will immediately notify countries about all regulatory actions taken on the basis of health or environmental concerns, and also provide countries with an annual summary of all pesticide regulatory actions. The policy explains that EPA will directly notify countries of the actions in advance and the State Department will notify embassies.

The policy also describes EPA's projects to support environmental protection and safe pesticide use in other countries. The policy discusses the scope of EPA's international technical assistance projects to support environmental protection and safe pesticide use in other countries. The United Nations' Prior Informed Consent procedures concerning banned and severely restricted pesticides are also discussed.

#### II. Background

##### A. Statement of EPA's Goals for International Pesticide Activities

EPA has two major goals for its international pesticide activities: To ensure the safety of the U.S. food supply; and to enhance the protection of public health and the environment from unreasonable adverse effects of pesticides, both in the United States and throughout the world, by promoting the sound management and regulation of pesticides. Specifically, EPA intends to take actions:

1. To protect the American consumer from illegal residues of pesticides on imported food products by informing countries who export food to the United States of our regulatory requirements, and by working with other U.S. agencies to ensure the quality of imported food.

2. To encourage international adoption of standards consistent with sound scientific risk assessment and to coordinate U.S. approaches, to the extent permitted by U.S. law, with those of other governments and international organizations.

3. To inform other governments about U.S. pesticide regulations and to assist them in the development of their own regulatory programs so as to better protect their public's health and environment.

4. To consider the work of other governments' regulatory programs in conducting our own regulatory reviews, so that we may benefit from this work, and promote internationally consistent regulations.

### B. Legal Authority

This notice sets forth EPA's final policy concerning the export of pesticide products and the notification to other countries of significant regulatory actions affecting pesticide sale and use in the United States. Section 17 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) contains the legal authority for EPA to carry out these policies. The provisions of FIFRA section 17 concerning exports of pesticides were first enacted in the Federal Environmental Pesticide Control Act of 1972, (Pub. L. 92-516) which amended FIFRA. The provisions for export notification (section 17(a)) were added in amendments to FIFRA through the Federal Pesticide Act of 1978 (Pub. L. 95-396).

An important part of section 17 is the provision of information to foreign purchasers and other governments concerning the registration status of pesticide products in the United States and EPA's conclusions regarding the safety of certain pesticide products. Section 17 of FIFRA currently mandates three systems of notification:

- (1) Labeling on exported products.
- (2) A notice to the foreign purchaser as well as the importing country of the export of an unregistered pesticide.
- (3) A notice to all countries of certain regulatory control actions taken by EPA. Section 17 also directs EPA to participate in international efforts in pesticide research and regulation. The provisions of section 17 concerning pesticide exports are presented below.

#### 1. FIFRA section 17(a). FIFRA section 17(a) provides as follows:

(a) *Pesticides and Devices Intended for Export.* Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act:

(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q)(1)(A), (C), (D), (E), (G), and (H), 2(q)(2)(A), (B), (C) (i) and (iii), and (D), 7, and 8 of this Act; and

(2) in the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of this Act, if prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

EPA interprets section 17(a) to provide authority for EPA to establish the specific requirements for labeling of exported pesticides and to establish the specific requirements and procedures for obtaining and distributing purchaser acknowledgement statements set forth in this policy.

#### 2. FIFRA section 17(b). FIFRA section 17(b) provides as follows:

(b) *Cancellation Notices Furnished to Foreign Governments.*—Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 3 of this Act and that could be used in lieu of such pesticide.

#### 3. FIFRA section 17(d). FIFRA section 17(d) provides as follows:

(d) *Cooperation in International Efforts.*—The Administrator shall, in cooperation with the Department of State and any other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.

#### C. Global Pesticide Market; Exports from United States; Pesticide Usage; Agricultural Imports

EPA estimates that 4 billion pounds of conventional pesticides (measured as active ingredients) are produced and used in the world annually. (Conventional pesticides include chemicals (other than wood preservatives) produced for, and marketed primarily as pesticides: this estimate excludes sulfur, petroleum distillates, and chlorine, all of which have substantial use both as pesticides and non-pesticides.) About three-fourths of the pesticides produced world-wide (3 billion pounds) is used for agricultural purposes. The remainder (about 1 billion pounds) is used for non-agricultural purposes.

The United States, along with other industrialized countries such as Germany and the United Kingdom, is a major exporter of pesticides. In 1989, the United States exported approximately 380 million pounds of active ingredient pesticides; this figure represents approximately 29 percent of overall U.S. pesticide production, and approximately 10 percent of the total world pesticide consumption, not including wood preservatives or disinfectants. An analysis conducted by the U.S. Department of Agriculture's Economic Research Service (ERS) estimates that in 1989, total U.S. pesticide sales were \$6.5 billion, of which \$2.0 billion were identified as export sales. The United States is also a major importer of agricultural commodities. In general, imports comprise about 15 percent of total U.S. agricultural product consumption. For certain items—coffee, bananas and cocoa, for example—imports are a much higher percentage of the total U.S. consumption. Pesticides are used in the production and storage of many of the imported food commodities that Americans consume.

#### D. Reasons for Review of EPA's 1980 Export Policy

1. *Health/environmental concerns.* EPA undertook a review of its export policy at a time of growing public concern both about pesticide residues, particularly in imported foods, and also about the contribution of American-made pesticides to health and environmental problems in the developing world. EPA is concerned about food safety, the quality of the global environment and about public health around the world, and believes that it was appropriate to review its policies to see how it could better address these health and environmental concerns.

In the United States and the international community, some have expressed the view that the United States should not permit the export of pesticides that are not registered for use in the United States. This view appears to be based on the perception that pesticides which are not registered for use in the United States, and which are manufactured in the United States for export to other countries, are inherently more dangerous than those that are registered for use here.

FIFRA provides EPA with only limited authority to prohibit pesticide exports. As a matter of policy, however, the Agency's position is that banning exports of unregistered pesticides will not necessarily solve the problems associated with pesticide use and misuse in other countries. The Agency's views in this regard have been based, in part, on the following four premises. First, controlling the export of products from the United States alone will not resolve the problems associated with pesticide use in developing countries. The United States is one of many pesticide exporters-exporting approximately 10 percent of the total world pesticide consumption. Many countries, including some developing countries, have the manufacturing capability to produce and export pesticides which have been banned or which are unregistered in the United States.

Second, EPA believes that it may be more effective to concentrate on controlling the management and use of all pesticide products, in order to reduce unnecessary exposure, rather than categorically banning certain classes of U.S. pesticides from international trade. Third, EPA's regulatory decisions are based upon risk/benefit evaluations specific to the United States. The risk/benefit balance in other countries may differ from the United States due to differences in growing conditions and pest control problems, as well as public health and environmental considerations. Thus, the fact that a pesticide is not registered in the United States may provide little indication of whether the pesticide poses a serious health or environmental threat when used in other countries. Fourth, pesticide manufacturers may not seek to register a product in the United States simply because there is no need for it here. For example, the product may

control a pest that is not a problem in this country or may be used on crops not commonly grown here. For these reasons, EPA strongly supports upgrading information and technical assistance to other countries to help them make sound decisions on pesticide use and regulation.

Concern about the export of banned or unregistered pesticides has been linked to fears that food imported into the United States will contain illegal residues of pesticides which cannot be used here. This possibility has been termed the "Circle of Poison." Data gathered from residue monitoring programs, however, do not lend support to the "Circle of Poison" theory. Although the data base is not as extensive as many would like, the results of food monitoring programs show that imported foods generally do not contain either elevated levels or a large number of pesticide residues, relative to domestic food samples. Furthermore, the levels that are found do not generally present any significant public health threat. (See statistics from food import monitoring programs, discussed below.) EPA, the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) have several programs in place to ensure the safety of imported food. These agencies are working together to address public concerns about the "Circle of Poison" and to share information to strengthen their monitoring and enforcement programs. These programs will be discussed briefly below.

**a. FDA's programs.** Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA is responsible for setting tolerances (maximum permissible residue levels) for pesticides in or on food and feed crops and in processed foods. While EPA establishes these tolerances, the FDA is responsible for enforcing tolerances. Under a surveillance monitoring program, FDA samples individual lots of domestically produced and imported foods and analyzes them for pesticide residues. Using five multi-residue testing methods routinely, FDA can detect and measure about half of the pesticides with EPA tolerances, as well as others that have no tolerances, plus numerous metabolites, impurities, and alteration products of both registered and non-registered products. For those pesticides with U.S. tolerances, single residue testing methods are available to test for those residues not detected by the multi-residue methods. Single residue methods are also used for surveys for specific pesticides of concern. The analytical methods used to measure the residues are generally capable of determining levels well below tolerance values. EPA's policy is that the Agency will not grant a food use registration under FIFRA or a tolerance under FFDCA unless there is a validated analytical method for detecting and measuring residues.

The FDA imposes various sanctions on domestic and imported foods found to contain illegal residues of pesticides. Domestic foods

are subject to seizure or injunction and imported foods may be detained at the port of entry when illegal residues are found. In the case of imports, "automatic detention" may also be invoked as a result of a single violative shipment. Automatic detention presumes that the violative condition may persist in subsequent shipments of the same food (same shipper or grower, same growing season). For this reason, subsequent shipments are automatically detained and required to be accompanied by a valid certificate of analysis from a private laboratory before they are allowed to enter the country.

The most recent statistics on FDA monitoring activities, which were compiled for Fiscal Year 1991 (October 1, 1990 through September 30, 1991) show that 19,082 samples were analyzed under the regulatory monitoring approach. Of these, 8466 were domestic and 10,616 were imports.

FDA collects two categories of samples—"surveillance" and "compliance" samples. Most samples gathered are surveillance samples collected when there is no reason to suspect that a particular shipment contains illegal residues. Compliance samples are taken for follow-up when a residue problem is known or suspected.

Of the 9,933 import surveillance samples analyzed, 69% had no residues detected, less than 1% had over-tolerance residues, and 2% had residues for which there was no tolerance for that particular pesticide/commodity combination. Fruits and vegetables accounted for 78% of the import surveillance samples. Of the fruits and vegetables tested, 65% and 68% of samples, respectively, had no residues detected. Each group had less than 1% of samples with over-tolerance residues. One percent of the fruit samples and 3% of the vegetables samples had residues for which there was no tolerance. No residues were found in 90% of the milk/dairy products group, and no samples were violative.

The majority of illegal residues found result from use of a pesticide on a particular commodity for which there is no tolerance, although tolerances for residues of that pesticide may exist for other commodities. In cases where no tolerance existed, or where the residues were over the tolerance level, sanctions were imposed.

FDA acquires information on pesticide usage in countries exporting food to the United States for use in planning and conducting its pesticide monitoring activities. FDA's primary source for such data has been the Battelle World Agrochemical Data Bank, a computer data base containing foreign usage data for about 20-25 countries. The Pesticide Monitoring Improvements Act of 1988 requires FDA to negotiate with the governments of major exporting countries for pesticide usage data, with the aim of enhancing FDA's ability to direct analysis toward those residues of specific pesticides known or thought to have been used on

particular commodities. Since the passage of the Pesticide Monitoring Improvements Act, FDA has expanded its coverage of imported foods sampled, testing a wider range of foods. EPA will also be able to regularly provide FDA and USDA with information concerning which countries are receiving certain pesticides from exporters in the United States, in accordance with the provisions of EPA's Class Determination 1-91, Identity of the Importing Country, (included in today's policy), FIFRA section 17(a)(2), and the regulations governing disclosure of business information to other Federal agencies at 40 CFR 2.209. (The confidential status of information submitted to EPA in purchaser acknowledgement statements is discussed in Unit III.C. of this preamble.)

**b. USDA's programs.** Responsibility for monitoring meat and poultry exported to the United States to ensure that it is wholesome and accurately labeled, in accordance with U.S. standards, belongs to USDA. The Food Safety and Inspection Service (FSIS) of USDA implements inspection and sampling programs as required by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

Federal meat and poultry inspection laws require countries exporting meat or poultry to the United States to impose inspection requirements at least equal to U.S. requirements. USDA's Foreign Programs Division evaluates foreign meat and poultry inspection programs through system reviews, including on-site reviews of plants in exporting countries. FSIS also conducts port of entry reinspection of meat and poultry products exported to the United States. Imported meat and poultry products are sampled for food chemistry and microbiological hazards as well as chemical residues (including pesticides) and drug residues. During 1990, 14,170 residue samples of imported product were analyzed for drug and chemical residues. Only 11 samples were found to contain violative levels.

**2. Congressional oversight.** In April 1989, the General Accounting Office issued a report to the Chairman of the Environment, Energy, and Natural Resources Subcommittee, Committee on Government Operations, of the U.S. House of Representatives, entitled, PESTICIDES: Export of Unregistered Pesticides is not Adequately Monitored by EPA (GAO/RCED-89-128). GAO identified problems in EPA's monitoring program regarding the section 17(a) purchaser acknowledgement statement requirement and reported that foreign countries were not being adequately notified on pesticides of concern in the United States pursuant to section 17(b). GAO recommended to the EPA Administrator that EPA take actions to strengthen its oversight of pesticide exports, including: (1) monitoring compliance with purchaser acknowledgement statement

requirements; (2) changing its enforcement policy concerning the export of unregistered pesticides under section 17(a); and (3) developing criteria and procedures to improve preparation and issuance of section 17(b) notices of control actions, specifically addressing the issue of what constitutes a "significant action" involving a pesticide.

GAO was critical of an exemption to the purchaser acknowledgement statement requirement of section 17(a), established in a 1980 Policy Statement (45 FR 50274), July 28, 1980. This 1980 policy exempted exporters of unregistered pesticide products which were "similar in composition and use pattern to a federally registered product" from the purchaser acknowledgement requirements of section 17(a)(2). GAO concluded that this policy exempted the majority of pesticide exports from the notice requirement, and also concluded that the exemption made it extremely difficult for EPA to monitor compliance with section 17(a).

On May 3, 1989, the Environment, Energy, and Natural Resources Subcommittee, held a hearing on the topic of pesticide exports. In addition to the issues raised in the GAO report, the Subcommittee requested that EPA officials discuss: trends in U.S. pesticide production and exports; EPA's performance and policies relating to the implementation, monitoring, and enforcement of section 17 of FIFRA; EPA's responsibilities under the FFDCA to establish pesticide tolerances (maximum level of pesticide residue permitted on food or feed); efforts by EPA to assist FDA and USDA in the identification of potentially adulterated food imports; U.S. involvement in international discussions relating to the Prior Informed Consent (PIC) concept (57 FR 58390, December 9, 1992); and EPA's efforts to provide technical assistance to foreign countries.

EPA officials testified at the hearing that EPA's implementation of the notification procedures needed improvement and agreed to review its program and propose alternatives that would be more effective in communicating to other governments the potential risks associated with certain pesticides. EPA also indicated that it had already concluded that notification systems alone would not resolve the types of problems associated with the use of pesticides in developing countries and therefore had also allocated a portion of its limited resources to providing technical assistance to developing countries. This export policy review was initiated at the conclusion of that hearing. On February 12, 1990 (55 FR 4956), EPA published proposed policy changes entitled the Pesticide Export Policies Review and proposed amendments to the 1980 policy. The proposals discussed possible revisions to export labeling requirements, confidentiality provisions, and international pesticide notifications.

On March 28, 1990, the Committee on Agriculture, Nutrition, and Forestry, of the U.S. Senate held a hearing on pesticide exports. The Committee invited EPA to address proposed legislation, the proposed Pesticide Export Reform Act of 1990 (S. 2227), as well as EPA's February 12, 1990 export policy proposals. At the hearing, EPA officials testified in support of strengthening the provisions of FIFRA governing the export of pesticides to address growing concerns about international trade in banned and severely restricted pesticides. EPA expressed support for amending section 17 of FIFRA to enable EPA to more fully implement the prior informed consent procedure of the United Nations Food and Agriculture Organization (FAO) and Environment Programme (UNEP).

At the hearing, the February 12, 1990 proposed policy changes were discussed, along with EPA's efforts to develop education and training workshops in pesticide regulation and management for other countries, especially developing countries. EPA also stated its wish to be consistent with the international Prior Informed Consent (PIC) procedures. (See 55 FR 4962.) PIC procedures are described in more detail in Unit III.E. of this preamble. (Copies of EPA's testimony for this and subsequent Congressional hearings on the export of pesticides are included in the public record for this policy statement, as discussed in Unit V of this preamble.)

EPA believes that improvements to current law are necessary to improve or help to ensure FDA and USDA have the ability to monitor imported food for illegal pesticide residues, regardless of the origin of the pesticide. Suggestions proposed to Congress by EPA would help to ensure that unregistered pesticides have been reviewed and approved by an OECD country, and that the data supporting the approval are available to potential importing countries to assist their decision-making. While EPA supports improvements to the current law, this policy statement is based upon current FIFRA requirements.

### III. Discussion of the 1980 Policy, the 1990 Proposal, Public Comments, and Responses to Comments

EPA received 40 sets of comments on its February 12, 1990 policy proposals: 18 from pesticide companies and industry, including trade associations; 2 from environmental organizations; 16 from foreign governments, 1 from a representative of the Organization for Economic Cooperation and Development (OECD); 1 from a consulting firm, and 2 from United States government agencies. The comments addressed all of the general areas of the proposed policy revisions. A brief discussion of the 1980 Export Policy, EPA's 1990 proposal, comments received and EPA's responses are presented below.

#### A. Section 17(a)(1)-Label and Labeling Requirements for Exported Pesticide Products

1. *Applicability of the label statement "Not Registered for Use in the United States of America" required by section 17(a)(1).* — a. 1980 policy. EPA's 1980 policy provided that in accordance with FIFRA section 17(a)(1), all unregistered pesticides must have labels or labeling which contain the statement "Not Registered for Use in the United States of America." The statement must be conspicuous and readable. The 1980 policy also required that this statement appear in both English and the language of the importing country.

b. 1990 proposal. EPA proposed clarifying that all unregistered products must comply with the labeling provisions of section 17(a)(1), and that all products not bearing a valid EPA registration number must state "Not Registered for Use in the United States of America" on their labels or labeling. The statement must be conspicuous and readable, and meet the requirements for multilingual labels as defined in § 168.65(b)(4) of this policy.

c. *Comments.* A number of industry representatives commented on the applicability of this requirement and ways to improve its utility. Three commentators thought that the "Not Registered for Use in the United States" labeling statement requirement did not currently apply to products which are claimed to be similar in composition and use to a U.S. registered product, and favored continuing that approach. Three other commentators also supported this approach. Two commentators suggested that EPA allow the statement to be expanded either to account for variations or to be reworded or supplemented, e.g., "this product is similar to a registered product..." The remaining commentators on this issue stated that the language "Not Registered for Use in the United States of America" should not be required on immediate product packaging since it would require relabeling in the importing country or the country of distribution. They suggested that exporters should be allowed to place this statement on the outside labeling, i.e., on the shipping or packaging containers.

d. *Response.* Section 2(q)(1)(H) of FIFRA requires that each unregistered exported product have the statement "Not Registered for Use in the United States of America" on the product label. Due to the range of interpretations expressed in the comments, EPA believes there is a need to clarify that point in this policy.

The statute prescribes that the label of an exported unregistered product must bear the statement "Not Registered for Use in the United States of America." Alternative statements which do not clearly inform the reader that the product is unregistered would not meet this requirement. EPA agrees,

however, that certain additional clarifying language could improve the usefulness of this statement, since the meaning of the term "not registered" may be unclear to handlers and users of pesticides in other countries. Therefore, EPA has decided that exporters may add language to the label to explain why the product is not considered to be a registered product in the United States. For example, where a particular product is unregistered because a labeled exported use includes a crop not included in the U.S. registration, it would be acceptable to add the statement "Not registered for Use on [unregistered use crop] in the United States of America." It would also be permissible to add clarifying language after the statement "Not Registered for Use in the United States of America" such as "For research use only."

In addition, EPA would not object to language which clarifies the registration status, such as adding the statement "No Longer Registered for Use in the United States of America" or adding information regarding the reason why the registration was dropped. The labeling statement must not, however, obscure the fact that the product is not registered for use in the United States and cannot be sold for use in the United States. EPA will consider as misbranded any exported unregistered product which does not contain the basic statement "Not Registered for Use in the United States of America" or to which any added labeling language is false or misleading, as in suggesting that the product is in fact registered.

As described elsewhere in this policy, the statement "Not Registered For Use in the United States of America" may be included on the supplemental labeling, rather than on the immediate product packaging.

**2. Applicability of the labeling requirement to research and development products.— a. 1980 policy.** The 1980 policy specifically stated that research quantities of pesticides are subject to the policy's labeling provisions.

**b. 1990 proposal.** EPA proposed to clarify that the labeling requirements of section 17(a)(1) applied to all exported pesticides without exception. EPA believed that clarification was necessary to ensure that exported R&D pesticide products that are exempted from other provisions of section 17 of FIFRA still meet the labeling requirements of section 17(a)(1).

**c. Comments.** Some commentors stated that it was their understanding that research and development (R&D) pesticides were not considered to be pesticides under FIFRA, according to the provisions of 40 CFR part 172 (Experimental Use Permits), and that such substances would therefore not be subject to any FIFRA requirements including labeling. Commentors also stated that since these chemicals would be used under highly controlled conditions by highly skilled individuals there would be little need for the required labeling. Commentors noted that

since these products were still in the developmental stage, many of the required statements could not be made.

Two environmental groups disagreed with the concept of exempting R&D chemicals from any labeling requirements. They believed that there should be tighter regulation of R&D chemicals because less is known about them than is known about commercial products.

**d. Response.** EPA disagrees with those commentors who stated that R&D pesticides are not pesticides regulated under FIFRA. The Agency does regulate R&D pesticides under FIFRA, even though the Agency may have determined that certain R&D pesticides would not be subject to all the requirements of FIFRA (e.g., See 40 CFR part 152).

In addition, EPA does not find any of the arguments against labeling requirements for R&D pesticides to be compelling. The minimal identity and safety information required on export labeling in section 17(a)(1), is useful in ensuring that such pesticides are properly identified during shipment and upon arrival in the importing country. The Agency believes that it is important to treat R&D pesticides that are exported consistently with our treatment of R&D pesticides in the United States. Therefore, when R&D pesticides are exported, such R&D pesticides are subject to the FIFRA section 17(a)(1) labeling requirements described in this policy.

In addition, the Agency has determined that in order to protect confidentiality, the exporter may choose to use coded information to identify the ingredients on the labeling of exported pesticide products shipped for R&D purposes. (See 40 CFR 168.65(b)(1)(iv) of this document.)

**3. Supplemental labeling.** Under section 2(p) of FIFRA, labels are written, printed, or graphic material "on or attached to the pesticide...or any of its containers or wrappers." Labeling, including supplemental labeling, refers to labels and any written, printed, or graphic material accompanying the pesticide or device at any time or to which reference is made on the label.

**a. 1980 policy.** In the 1980 policy, exporters were allowed to use supplemental labeling to meet label requirements when there were conflicts between United States and foreign label requirements. The 1980 policy provided that supplemental labeling may be attached to or accompany the product container or shipping container. The policy emphasized that the Agency intended to be as flexible as possible on this issue. Exporters were permitted to use a variety of types of labeling to comply with the requirements of FIFRA, as long as the labels or labeling, when taken together, conform to the FIFRA section 17(a)(1) requirements.

**b. 1990 proposal.** EPA proposed maintaining its 1980 policy regarding supplemental labeling of exported pesticides. This policy allows the placement of label

statements either on the label or on the labeling (i.e., attached material) as long as the labels and labeling, taken together, fulfill the requirements of FIFRA section 17(a)(1). EPA alternatively proposed to clarify that certain language had to appear on the immediate container unless there was a direct conflict with foreign labeling requirements.

**c. Comments.** The majority of commentors favored continuing the 1980 policy, but also indicated a need for clarification of when supplemental labeling is allowed, what may be included in supplemental labeling, and what supporting documentation may be needed to allow the Agency to ensure compliance.

While one foreign government commented in favor of continuing the existing policy, most of the comments on supplemental labeling were received from industry. All of the comments from industry representatives supported reducing the label requirements for exported pesticide products, and allowing exporters to place the majority of the required statements on attached labeling. Two commentors stated that exporters should be allowed to place all bilingual or multilingual statements on supplemental labeling, and that it should be permissible to place on immediate containers, labels only in the language of the country of intended use. One commentor stated that the policy should explicitly allow this. Two commentors stated that if the purchasing country was different from the country of final destination, the purchaser would never see the immediate containers and thus labeling in their language would be of no use. The commentors said that placing U.S.-required statements on immediate containers would simply mean that those containers would have to be relabeled at a later date.

Three commentors stated that the proposed multilingual requirement for labels (55 FR 4971) would cause problems unless supplemental labeling were generally allowed. Two cited situations where such products would have to be repackaged or reprocessed overseas before final sale and use. The other commentors mentioned that having several translations on the label would take up too much space and crowd the labels. Two commentors stated that imposing U.S. product label requirements would interfere with the ability of foreign governments to regulate pesticides. One of these commentors suggested that requiring U.S. labeling statements on exported products would insult foreign national sovereignty. The other stated that their customers were incredulous that certain FIFRA-required statements would have to be on the immediate container labels of products they purchased from U.S. manufacturers. Two commentors said that once a product is exported, EPA would not be able to enforce label provisions.

**d. Response.** The Agency continues to support the position stated in its 1980 policy statement that EPA will allow exporters to

meet the labeling requirements in FIFRA by the use of supplemental labeling. By this policy, EPA makes it possible for exporters to also meet the label and labeling requirements of foreign purchasers and regulatory authorities.

EPA agrees with commentors who state that it should be permissible to label immediate containers in accordance with the requirements of the country of intended use, and to include any FIFRA required statements on supplemental labeling which must accompany shipping containers. EPA also agrees that the multilingual labeling requirements may be met through supplemental labeling. The multilingual requirement is intended to ensure that appropriate information is available to all persons who come in contact with a pesticide, and attaching that information to shipping containers will accomplish this purpose while the pesticide is being transported. This also allows the product to be labeled in a manner that is considered appropriate by the importing country.

Finally, EPA believes that it is not appropriate to require evidence that a FIFRA label actually conflicts with the labeling requirements of a foreign country in order to allow supplemental labeling. The government of a foreign country may prefer or require that the label be only in the language of their country, that the label present certain information in a specified format, or that the label conform to an accepted international label scheme.

Consequently, EPA has decided that the labeling requirements under section 17(a)(1) may be met either with a label attached to the product container or with supplemental labeling attached to the shipping containers. The supplemental labeling must be attached to the immediate product container or the shipping container at all times when it is shipped or held for shipping in the United States. For example, placing required information on the supplemental labeling of exported pesticides would be considered appropriate in the following situations: where the immediate pesticide containers are labeled to meet foreign purchaser requirements or international labeling conventions; where the producer uses supplemental labeling to meet multilingual labeling requirements; or where the producer believes there may be problems meeting the labeling requirements of foreign countries if U.S. labeling information is included on the immediate product containers. The exporter must only determine which labeling provisions are not met through information on the label attached to the immediate container and meet those requirements through supplemental labeling. Where the supplemental labeling and container labeling taken together meet the FIFRA requirements, the shipment will be considered to be in compliance with FIFRA.

#### 4. Expansion of Language Requirements for Labels from Bilingual to Multilingual.—

a. *1980 policy.* FIFRA section 2(q)(1)(E) requires that "any word, statement, or other information" required pursuant to its authority must be "...in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use." EPA's 1980 policy statement interpreted this language to require bilingual statements, in English and the language of the importing country, for: (i) The warning and caution statements, (ii) the ingredient statement, (iii) where required, the word "poison" and the statement of practical treatment, and if required, (iv) the statement "Not Registered for Use in the United States of America."

The 1980 policy stated that "any language in which official government business is conducted in the country or which is the predominantly spoken language of the country is acceptable as the second language on the label." 45 FR 50275 (July 28, 1980.)

EPA's authority to establish bilingual labeling requirements for exported pesticides was affirmed by an EPA administrative law judge. See In the Matter of Shield-Brite Corporation, (Docket No. FIFRA-90-H-02, June 28, 1991).

b. *1990 Proposal.* EPA proposed to require that labeling statements, which are currently required to be bilingual, be multilingual. As such, the labeling statements would have to appear in English, in the language of the purchaser's country, and if different, in the language of the country of final destination. This was done to address those situations where a product is exported to more than one country, as well as when the country of final destination is different from the country to which it is initially exported.

c. *Comments.* EPA received a number of comments on this issue. Approximately 12 commentors supported retaining the current bilingual labeling requirements. Two environmental groups and two countries strongly supported multilingual labeling. One commentor suggested that all precautionary statements be multilingual. Nine industry commentors strongly objected to multilingual labeling as impractical, unnecessary, burdensome, and stated that it would put the United States at a competitive disadvantage. Two countries favored multilingual labeling, stating the importance of readable labels at use sites. Another country stated that it had its own strict requirements for labeling to be in its own language, but did not explain whether bilingual or multilingual label statements were permitted. One country responded that it expected labels to be in its own language.

Pesticide industry commentors expressed strong objections to this proposal and expressed a preference for bilingual labeling. Several stated that only English and the language of the country of final destination should be on the label since the intermediate country only transfers the pesticide. Other industry commentors stated that the label

should be bilingual but not in the language of the country of final destination because this is often not known.

Several commentors stated that this requirement would cause problems in the case of reformulated technical active ingredients, since labeling of technical products would not be sent with the reformulated products. In addition, it is often difficult to anticipate the final destinations when technical products are shipped from the United States.

d. *Response.* EPA believes that multilingual labeling is required for the communication of important information on the safe and effective handling of pesticides. However, EPA acknowledges that there are likely to be situations where it is impractical for the U.S. exporter to know the identity of each country to which a pesticide may eventually be shipped. Therefore, an exporter must only include the language of each country to which the exporter knows, or can reasonably be expected to know, that the product will be shipped. For this reason, EPA is qualifying the requirement by adding the phrase "if known, or reasonably ascertainable" when referring to the need to include the language of the country of final destination.

Examples of when the exporter can reasonably be expected to know the destinations of a shipment, include but are not limited to the following: there is documentation in the exporter's files, e.g., sales or shipping contracts, which specify the destination of the specific shipment; an exporter's history of transactions with a particular customer would indicate where particular pesticides have been shipped and indicate where this shipment is likely to go; there is documentation in the exporter's files which indicates that a pesticide is being shipped to a country as an intermediate destination and will be reshipped to other countries for importation, in which case the other countries are considered the final destination.

EPA acknowledges that where a product is a concentrated active ingredient shipped to a foreign purchaser for reformulation, the U.S. exporter may not be able to anticipate all possible reformulations and their destination. For example, if a technical grade active ingredient is exported for reformulation into end-use products in the importing country, the exporter may not know where the end-use products will be shipped. In this case, the exporter would only be required to label the product in English, and the language of the importing country. Note, however, that if the exporter knows, or can be reasonably expected to know, that the active ingredient is being shipped to an intermediary who will ship it to another country where reformulation would take place, multilingual labeling would be required in English, in the language of the country of the intermediary, and in the language of the country of the reformulator, who is considered to be the final destination.



Although EPA believes that multilingual labeling will help to communicate more information to people who come into contact with pesticides during shipment, handling, and use, EPA also recognizes that there are limitations to the usefulness of multilingual labeling. Some users of pesticides may not be able to read, and for those people, pictures or symbols may be more effective in conveying use and safety information. As such, EPA has reviewed and strongly supports the Guidelines on Good Labeling Practice developed by the Food and Agriculture Organization of the United Nations, March 1985. These guidelines were prepared with the intention of assisting people who prepare pesticide labels, in communicating the essential elements of the safe and effective use of pesticides to end-users.

The FAO guidelines recommend communicating information on hazard by using the pictorial representations indicating toxicity, flammability, explosiveness, oxidation, irritancy, and corrosiveness. In addition, international symbols used to indicate various physical properties have been combined with short hazard classification statements, used in the World Health Organization (WHO) Hazard Classification System. WHO's hazard classification is based on the hazard presented by the formulated product (e.g., a WHO Class Ia pesticide active ingredient could be in Class II when formulated.)

The guidelines also recommend using color coding, based on the toxicity of the product, and should be linked to the WHO Recommended Classification of Pesticides by Hazard. The FAO guidance suggests placing a band at the bottom of the label, occupying not less than 15% of the label area, in the appropriate color for the hazard classification. For pesticides which fall into the WHO Class Ia or Ib, red is recommended. Pesticides which are classified as WHO Class II should have a yellow band, and pesticides in WHO Class III, a blue band. Pesticides in WHO Class III which are technical products unlikely to present hazard in normal use (Table 5 of WHO classification Guidance), should have a green band.

EPA is considering whether to also require the WHO hazard classification, along with the appropriate color code and pictograms, on the label or labeling of pesticides for export. This issue may be addressed in a future Federal Register.

Producers of pesticide products for export are reminded that they may label products according to WHO guidelines in order to meet the requirements of foreign purchasers, as long as the labeling requirements of section 17(a)(1) as described in this policy are met. If necessary, supplemental labeling as described in this policy may be used in order to meet the labeling requirements of section 17(a)(1) when immediate containers are labeled in accordance with WHO guidelines.

**5. Modification of the use classification statements.**— *a. 1980 policy.* FIFRA section 2(q)(2) requires that pesticide product labels contain a statement of the use classification under which the product is registered. The 1980 policy stated that the use classification must appear on the labeling of the pesticide; e.g., for restricted use pesticides, the statement "Restricted Use Pesticide" must appear on the label or labeling. However, summary statements regarding the terms of the restriction, e.g., "For retail sale to and application only by Certified Applicators..." were not required.

*b. 1990 proposal.* EPA did not propose any changes to the use classification statement labeling requirement.

*c. Comments.* A number of commentors requested clarification of what information EPA might allow to explain use classification statements to make them more understandable in other countries. Several commentors both from industry and environmental groups stated that terminology normally included in the use classification statement of products registered in the United States would be confusing to importing countries. Some commentors stated that the term "restricted use pesticide" might be confused with the UNEP/FAO term "severely restricted" which has a different meaning from "restricted use pesticide" under FIFRA. A suggested modification was that EPA allow the exporter to include the terms of the restriction with this statement.

*d. Response.* In the 1980 policy statement, EPA stated that all of the conditions applicable to a use classification need not be listed on the labeling. EPA believed that such conditions may not have much meaning outside of the United States. For example, the statement "For retail sale to and use only by Certified Applicators..." would have little meaning to someone not familiar with U.S. pesticide regulations. The comments EPA received suggested that even the basic terms used in use classifications (e.g., "restricted use pesticide") can result in confusion. Therefore, EPA agrees that some clarifications should be allowed, as long as they do not obscure the classification statement. Thus, it is permissible to add explanatory language which accurately explains the meaning of a use classification. For example, the statement "restricted use pesticide" may be expanded to read:

"Restricted in the United States of America to use by certified applicators" or "Restricted Use Pesticide. In the United States this product is restricted to use by applicators determined by each state to be competent in pesticide application, and human health and environmental consequences of misuse." Note, however, that if such explanatory language falsely represents or is misleading regarding the use classification in the United States, the product will be considered misbranded. EPA also wishes to point out that a use classification

should only be listed if one has been assigned pursuant to the U.S. registration.

*6. Identities of parties required on the label.* The 1990 proposal provided guidance on elements which must appear on the label or labeling of each exported product (55 FR 4971, February 12, 1990.) Under "Identity of Parties," the proposal read: "Name and address of the producer, registrant (if any), and the person for whom the pesticide was produced, must appear in the labeling." This sentence should have read "Name and address of the producer, registrant (if any), or the person for whom the pesticide was produced must appear in the labeling." The correct language is being used in the final policy.

#### *B. FIFRA Section 17(a)(2)-Procedures for Exporting Unregistered Pesticides—Purchaser Acknowledgement Statements*

*1. Similar in composition and use exemption.*— *a. 1980 policy.* The 1980 policy created an exemption from the requirement to obtain a purchaser acknowledgement statement for unregistered pesticides which were minor variations on formulations registered in the United States, which contained only active ingredients registered in the United States, and which had similar use patterns to U.S. registered products. To be considered similar to a U.S. registered product in composition and use pattern, a pesticide product had to contain the same active ingredient or combination of active ingredients, and be in the same category of toxicity as a federally registered product. The use pattern also had to be similar to the use pattern of the federally registered product to which it was being compared.

*b. 1990 proposal.* EPA proposed to modify or to eliminate the existing exemption from the purchaser acknowledgement requirement for products substantially similar in composition and use to currently registered products. If the exemption were retained, EPA proposed that the burden of substantiating the claim remain with the exporter, and that any similarity claims be supported by documentation. The Agency was also considering whether such documentation should be maintained in records which would be made available to EPA upon request, or whether the documentation should be submitted to the Agency.

*c. Comments.* Two environmental groups advocated eliminating the exemption, citing the ambiguity of the exemption criteria, the burden of proving compliance with whatever criteria might be adopted, and the opinion that the exemption appears to be a "loophole" for unregistered products. The commentors suggested that the regulated community should not decide which products did and did not require notification. One foreign government also supported eliminating the exemption due to the ambiguity of the



exemption criteria. One industry commentator stated that the exemption created problems for the regulated community and stated that if the exemption were retained, it must be better defined.

One foreign government and an OECD representative supported keeping the exemption to preserve the utility of notices sent to foreign governments. However, they expressed enforcement concerns if the exemption is maintained, since they felt that it would be difficult to ensure that the exemption is properly used.

Most of the industry commentators were in favor of maintaining the exemption. Several of these commentators said that removal of the exemption would result in increased burden but they did not elaborate beyond the estimates EPA published in its proposed policy. In addition, some commentators believed that eliminating the exemption would result in potential trade disadvantages since foreign firms would not be required by their governments to obtain such notifications. Several stated that they did not perceive any potential benefits from the elimination of the exemption.

Proponents of the exemption cited instances where products, which are otherwise identical to U.S. registered pesticides, would be subject to notification as "unregistered" because of: (1) Relabeling or repackaging to conform with metric weight formulations, including possible rounding-off differences resulting in slightly different technical active or inert concentrations; (2) minor inert modifications including color or odor modifications to meet customer specifications; and (3) labeling for uses for which there are no U.S. applications such as for certain tropical crops. Some commentators pointed out that in these cases the relevant safety data which would apply to registered pesticides are just as applicable to the unregistered "similar" products. It was stated that custom blending to meet foreign formulation requirements would often result in products that are not identical to the U.S. product, although the product is otherwise the same.

Many proponents of the exemption stated that a clearer definition of "similar" was needed. Several asked that explicit criteria be made available. One stated that EPA needed to propose such a clarification for public comment. Most commentators from industry did not object to the proposal that exporters maintain records to substantiate similarity claims, but many objected to a reporting requirement.

**d. Response.** EPA has concluded that the exemption should be eliminated. As was pointed out by some commentators, the exemption creates compliance problems for industry and has also proven to be difficult for the Agency to enforce. EPA believes that elimination of the exemption is the best way to resolve the difficulties associated with compliance, both for the regulated community

and for EPA. In addition, the Agency believes that elimination of the exemption will provide the importing countries with better information on pesticides exported from the United States.

At the time that EPA published the proposed policy it believed that compliance and enforcement problems could be partially solved by clarifying that the burden of proof lies with the person asserting similarity. However, even with such provisions, including requiring the exporter to substantiate claims of similarity, EPA has determined that arriving at consistent interpretations would still be extremely burdensome for the Agency, and confusing to the regulated community and other governments.

In the proposed policy, EPA expressed concern about whether eliminating the exemption would raise problems in terms of increased burden on exporters and the governments of countries receiving the purchaser acknowledgement statements in terms of the number of notices that may be required. EPA explicitly requested comments on this issue, including any potential benefits to importing countries. While several commentators mentioned increased burden, none provided information beyond the estimates presented by EPA. Those burden estimates were small and not judged to be important enough to offset the compliance and clarity problems associated with the exemption. EPA believes that only a small number of additional notices would be required annually, and the burden imposed by each notice is not large. EPA does not, therefore, find the arguments based on increased burden on exporters to be compelling.

EPA was concerned that eliminating the exemption might detract from the usefulness of the purchaser acknowledgements statements to receiving governments. Since transmittals of statements to foreign governments will be made by EPA, (See discussion of EPA's transmittal of section 17(a) notices, in Unit III.B.6. of this preamble) the Agency intends to continue to review its internal procedures to determine if there are ways to increase the usefulness of the statements to other governments, and to make them easier to process. For example, EPA is considering attaching a revised cover sheet, with more detailed information than the one currently used, which would explain the purpose of the purchaser acknowledgement statements to help countries distinguish them from other international notifications, such as section 17(b) and PIC notices. EPA may also specially identify statements which the Agency has reason to believe may be of specific interest to importing countries, such as statements associated with chemicals which are identified on international lists as posing special concerns. EPA believes that such steps may largely offset any potential burden or loss of utility to other governments

that could otherwise result from elimination of the exemption.

For the purposes of FIFRA section 17(a), EPA will consider products to be registered if they are registered under section 3 of FIFRA, or if they were once registered and are being sold under section 6(a)(1) of FIFRA. Except as discussed in this policy, any variations in the formula of the export product from the formula of the U.S. registered product, or any uses or claims on the export product's label which are not consistent with the uses or claims stated on the label of the U.S. registered product, render the export product "unregistered" and subject to all the requirements for exporting an unregistered product pursuant to FIFRA section 17(a). As discussed later in this section, certain modifications to the labeling, packaging, or composition will not cause an otherwise registered product produced solely for export to be considered unregistered.

Applications for pesticide registrations under FIFRA must be accompanied by a copy of the product's proposed labeling, including uses and claims, and a full description of tests made and results thereof in support of such claims. A pesticide's formulation, uses and claims which are stated on its labeling are all essential components of the pesticide's U.S. registration. EPA believes that the product labeling is an important reference point for determining whether or not any pesticide product, including one produced for export, is registered in the United States. EPA's pesticide labeling regulations specifically require that an approved product label must be attached to the immediate pesticide product container. This is to ensure that the label information is transmitted and understood under customary conditions of sale and use.

EPA understands that when pesticide products are exported, it may not be practical to label the immediate container with the U.S. label without defeating the packaging or labeling needs of the foreign purchaser. For example, the purchaser may need to label the product container with a label meeting the requirements of the country of import. Although EPA believes that the labeling is critical in identifying a product as registered, it is not EPA's intent to consider exported products unregistered simply for failing to attach the U.S. approved label to the immediate product container. Therefore, EPA will allow registered products to still be considered registered for the purposes of this policy when the labeling approved under the U.S. registration is not directly attached to the immediate product container, as long as that labeling accompanies the product at all times, i.e., as supplemental labeling. If an exported product does not bear the FIFRA section 3 labeling either on the immediate product container or as supplemental labeling, it will not be considered registered for the purposes of this policy. The sale or distribution of such a product without meeting the

acknowledgement statement requirements of section 17(a)(2) will constitute the sale and distribution of an unregistered pesticide in violation of FIFRA section 12(a). (Note: section 2(q)(1)(C) of FIFRA precludes any person from exporting a product that is in imitation of, or is offered for sale under the name of, another pesticide. This means that a person cannot use the pesticide product labeling approved under another person's registration in order to export their own product as a "registered" product.)

When a product is claimed to be a registered product, and is accompanied with the approved U.S. labeling, any labeling material which is in addition to the U.S. label (as would be the case when the intermediate container is labeled in accordance with foreign purchaser specifications) must be compatible with the U.S. labeling. Except as discussed in this policy, if the product labeling indicates a different formulation from the registered product, or states new uses or claims, the product will be considered to be a different product and not registered under FIFRA. The presence of contradictory labeling statements associated with the same product will also render that product misbranded.

Export product labeling that states information concerning composition, claims or uses which are within the scope allowed by the U.S. label will not be considered to be in conflict with the U.S. label. For example, if the export label of a U.S. registered product lists some, but not all, of the U.S. registered uses or crop applications, the registration status for purposes of this policy would not be affected. Similarly, if the export product label states application rates that are allowed under FIFRA when the registered product is used in the United States, the product would still be considered registered.

If the export labeling states application rates in metric units, the product's regulatory status will not change if the metric measurements are an accurate conversion from the U.S. units. An exporter of a U.S. registered pesticide may add new uses to the label of that product for export purposes, without triggering the requirements of section 17(a)(2), as long as the new uses are within the same general use patterns as those for the registered product. (Pesticide use patterns are listed in Appendix A to part 158-Data Requirements for Registration: Use Pattern Index. The general pesticide use patterns are: terrestrial food crop and terrestrial nonfood crop; greenhouse food crop and greenhouse nonfood crop; aquatic food crop and aquatic nonfood crop; indoor use; and forestry use.) Adding new uses to the label which change the use pattern, such as changes from non-food to food use, outdoor to indoor use, or terrestrial to aquatic use, render the product unregistered and subject to the requirements of section 17 for unregistered products. If the new use added to the label is a food or feed

use, a tolerance must already be established for the use of that pesticide in or on that commodity or the product will be considered unregistered and subject to the requirements of section 17(a)(2).

If the export product label contains statements regarding the formulation or composition of the product which differ from that allowable under the U.S. registration (i.e. statements that differ from the statement of ingredients listed in the certified statement of formula), the product will be considered unregistered. For example, EPA will consider any stated concentrations of any active ingredients which fall outside the certified limits for that product to render that product unregistered. EPA will also consider the product to be unregistered when the label statements indicate the presence of active or inert ingredients which are not in the U.S. registered product, or when the label does not list active or inert ingredients which are in the U.S. registered product. EPA may determine such products to be misbranded and adulterated. EPA wishes to emphasize that except as provided in this policy, any differences in formulation or composition between the exported product and that indicated in the confidential statement of formula for the registered product, including inert ingredients, will cause the exported product to be considered unregistered. In addition, any differences in formula or composition must be reflected in records which show the complete formula of the export product, in accordance with the requirements of 40 CFR 169.2 and this policy.

EPA recognizes that certain modifications to the composition of an export product should not render the export product "unregistered" and thus subject to the requirements of FIFRA section 17(a)(2). Therefore, EPA has decided that a change in the color or fragrance of the export product will not affect the product's registration status, as long as certain conditions are met. The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.1001, and the dye must not be a List 1 inert. (List 1 inerts are those inerts which the Agency has identified as presenting toxicological concerns. The classification of inerts is explained in EPA's Policy Statement on Inert Ingredients in Pesticide Products, 52 FR 13305, April 22, 1987.) The change in fragrance must result only from the addition of a chemical included on the list of chemicals exempted from the requirement of a tolerance (40 CFR 180.1001) and the added chemical must not be a List 1 inert. In addition, the change in fragrance must not result in a pesticide product containing a food or food-like fragrance. (See "Food Fragrances in Pesticide Formulations," EPA's Office of Pesticide Programs Policy and Criteria Notice number 2155.1, November 20, 1975.)

EPA also recognizes that there are instances where a company may need to slightly modify the composition of one of its U.S. registered products for export purposes. EPA will not consider a company's modification of its registered product to render that product "unregistered" in the following situation. An exporter, who is also the registrant and/or manufacturer of a U.S. registered pesticide, (other than pesticide products intended for public health uses which are required or conditionally required to submit efficacy data pursuant to section 158.640), may decrease the percentage of the active ingredient(s) of that product by adding a List 4 inert ingredient, without causing that product to be considered "unregistered" and triggering the requirement to obtain a purchaser acknowledgement statement. In EPA's Policy Statement on Inert Ingredients in Pesticide Products, EPA included inert ingredients on List 4-a list of inert ingredients posing minimal hazard or risk-if the inert ingredients were generally regarded as innocuous. (52 FR 13305, April 22, 1987.)

Such limited modifications may only be made by the registrant and/or the manufacturer of the U.S. registered product. As discussed above, EPA's 1980 Pesticide Export Policy exempted exporters of unregistered pesticide products from the purchaser acknowledgement statement requirement for products which the exporter claimed were "similar in composition and use pattern to a federally registered product." EPA has concluded that only the registrant and/or the manufacturer of the product may be able to legitimately claim that its export product is the same composition as its own federally registered product, except for the addition of List 4 inert ingredients. EPA has concluded this because only the registrant and/or manufacturer have access to the product's confidential statement of formula thereby making it possible for them to know the extent to which the modified product differs from the registered product. Pesticide exporters are no longer permitted to claim that their product is similar to another company's registered product and thereby exempt themselves from the purchaser acknowledgement statement requirement.

EPA's pesticide registration regulations also provide that certain changes may be made to a product's composition, labeling or packaging, without notification to or approval by the Agency. (See 40 CFR 152.46(b)). These changes include any changes in package size and label net contents, provided no change in use directions or requirement for child-resistant packaging would be necessary for the product to be registered for use in the United States. For example, if child-resistant packaging is required for a particular pesticide product in the United States, and the product will be exported without child-resistant packaging, the product would be considered unregistered and therefore subject to all the requirements of FIFRA section

17(a), including the requirement for a purchaser acknowledgement statement.

If an exporter needed to repackage a product in a size to meet a foreign purchaser's specifications, that modification would not affect the registration status of the export product. Other modifications to the label used for export purposes which will not affect the export product's registration status are: the use of metric units for net contents, dosages, and other numeric expressions; the use of a different format for the label, provided that the information does not contradict the U.S. label; revision of non-mandatory U.S. label statements, consistent with 40 CFR part 156, including additions or changes required by other Federal statutes or regulations; a change of the name or address of the registrant, except for a change resulting from transfer of ownership, which requires that a registrant keep his name and address current with the Agency; and any correction of typographical or printing errors that appeared on the U.S. labeling. (See 40 CFR 152.46(b)).

Finally, EPA recognizes that there may be situations where minor discrepancies between an export label and the U.S. registered label result from the translation of statements or the conversion of units. Where such differences are not significant, EPA does not believe that they should affect the registration status of the product for purposes of export. However, except as provided in this policy, differences which indicate new uses or claims would be considered to be significant and to render the product unregistered. EPA wishes to emphasize particularly that warning or cautionary statements that translate to a lower level of warning or caution than that indicated on the U.S. labeling will be considered to be significantly different.

EPA believes that in addition to the flexibility discussed above, this policy will provide importing countries with clearer, more accurate information on the registration status of the pesticides being exported from the United States, consistent with the requirements of the statute.

**2. EPA treatment of exports of unregistered pesticides for research purposes. — a. 1980 policy.** The 1980 policy stated that experimental use products will be considered unregistered, therefore requiring signed purchaser acknowledgement statements prior to export. However, small amounts of pesticides exported only for research purposes would be considered exempt from the purchaser acknowledgement statement requirement.

**b. 1990 proposal.** EPA proposed that pesticide products exported solely for research purposes would not be considered to be in violation if no purchaser acknowledgement statement was sent if the exporter met certain recordkeeping requirements to substantiate the claim that a product is shipped for research purposes. In addition, EPA proposed that the exporter

should bear the burden of demonstrating that the pesticide qualifies for the research exemption.

**c. Comments.** Two environmental groups stated that research and development (R&D) products should not be exempt from the requirements of section 17(a)(2). They stated that such products constitute "unknowns" and that consequently it is very important that foreign governments be aware of their importation. Other commenters stated that R&D chemicals tended to be small quantities which would not cause great potential health or environmental risks.

One industry commentator stated that it would be simpler to obtain the purchaser acknowledgement statement than to substantiate R&D use abroad, and consequently supported eliminating the exemption. However, all other industry commentators who addressed this issue stated that the exemption should be maintained, and that export for small scale R&D use could be substantiated. Several supporters of the exemption mentioned that requiring purchaser acknowledgement statements where R&D chemicals are being exported for testing, would provide the locations of potential markets to their competitors, and cause a company competitive harm. Several commenters stated that it was their belief that R&D pesticides were not "pesticides" under the meaning of FIFRA, as stated at 40 CFR 172.3, and hence were exempt from any of the requirements of section 17 including both labeling and acknowledgement statements. (See discussion in Unit III.A.2.d. of this preamble.) Some commenters stated that they did not believe that there was a great need for notification of other governments of R&D exports because R&D products are used in tightly controlled situations by highly qualified persons. They did not believe that there was a significant chance for misuse or other risks.

Finally, some commenters were concerned that if there is no exemption for the export of R&D products, particularly if notices are made publicly available, product confidentiality could be jeopardized. These commenters pointed out that proprietary knowledge is treated differently in some foreign countries than it is in the United States. Therefore disclosure of the identity of research products carries a much greater risk of competitive harm internationally than would be the case in the United States.

**d. Response.** As discussed earlier, EPA disagrees with the commenters who stated that exported R&D pesticides are not considered to be pesticides under FIFRA. Research pesticidal products are considered to be pesticides regulated under FIFRA, unless EPA makes determinations otherwise that are applicable to the specific products in question.

EPA does, however, believe that under many research conditions involving small quantities, R&D pesticides will be used in a

manner that renders the risk of potential adverse effects to human health or the environment negligible.

EPA acknowledges the concerns that some commenters had regarding the export of "unknown" pesticides to countries without their governments having the benefit of purchaser acknowledgement statements. EPA believes that governments should be notified when there are large-scale research and development applications or applications where there is a strong potential for direct human or dietary exposure. For the reasons stated above, however, EPA does not believe that it is useful to impose this requirement in the case where only small scale controlled uses are intended.

Consequently, EPA will not consider exports of R&D pesticides intended for small-scale research application (as defined below) to be in violation of section 17(a)(2) if no purchaser acknowledgement statement was sent. EPA believes that it is critical to define what is meant by small-scale research applications and is addressing this issue in this policy.

**3. Definition of small-scale research application. — a. 1980 policy.** The 1980 policy did not include any specific definition of small-scale research product application.

**b. 1990 proposal.** EPA proposed to provide specific criteria to define when an R&D export would not be considered to be in violation of the purchaser acknowledgement requirements of section 17(a)(2) of FIFRA. These criteria were based on the scope of the application and other factors relating to possible human contact or dietary exposure rather than on the physical quantity involved since the actual amounts of pesticide could vary considerably based on type of pesticide, concentration, and other factors. Exports of pesticides for research purposes in quantities that would not normally require notification of EPA and issuance of an experimental use permit if the use were in the United States, would not be considered to be subject to the purchaser acknowledgement requirement of section 17(a)(2).

**c. Comments.** One foreign government and several industry commenters expressed general approval of EPA's proposed criteria for defining small-scale R&D quantities based on use, although one of the commenters suggested that a closer adherence to the criteria cited at 40 CFR 172.3 should be used. Another stated that there needed to be some further clarification of what was intended in the criteria, i.e., that the limits on proposed use be on a "per-country" rather than a "per-pesticide" basis.

One commentator suggested that it was not appropriate to use the proposed criteria. The commentator stated that these criteria were designed for the United States, and only accurately define research applications in the United States. They would not, therefore, necessarily be applicable worldwide.

d. *Response.* EPA acknowledges that the regulation of R&D pesticides may vary in different countries, but believes that the advantages of using a single set of criteria that are consistent with those in place for similar testing of R&D pesticides in the United States outweigh any disadvantages. The Agency did not wish to use significantly different criteria from those used in the United States unless there were compelling reasons to do so.

EPA agrees that it is necessary to clarify how to interpret these criteria when there are multiple shipments to multiple countries. EPA believes that the most consistent approach is to consider separately product shipments within a calendar year to multiple countries. If the R&D use of the product shipped within a given calendar year by an exporter to a particular country exceeds the criteria stated in this policy, EPA will consider failure to submit a purchaser acknowledgement statement to be a violation of section 17(a)(2). For example, if within a calendar year, an exporter is shipping a pesticide for research purposes, and the product may be used on more than 10 acres (4.05 hectares) within the country of import, EPA would consider failure to submit purchaser acknowledgement statements regarding those shipments to be violations of section 17(a)(2). If a shipment, or series of shipments over the course of a calendar year to a foreign purchaser for R&D use in one country meets the criteria outlined above, separate shipments to other countries would be considered separately.

The comments generally favored the proposed criteria, and EPA is therefore including the proposed criteria in the final policy. EPA is clarifying that these criteria concern only the acknowledgement requirements and are not pertinent to other FIFRA requirements, such as labeling required under section 17(a)(1).

4. *Substantiation and/or verification of small-scale R&D exports.* — a. *1980 policy.* The 1980 policy did not include any specific criteria for defining small-scale pesticide export for research purposes only.

b. *1990 Proposal.* EPA proposed that records substantiating claims for small-scale R&D pesticide exports be retained for 3 years and be available for inspection, or, alternatively, that information substantiating such claims be submitted to the Agency.

c. *Comments.* Several commentors stated a strong preference for a recordkeeping requirement rather than any new reporting requirements. One commentor stated that reporting on a case-by-case basis could be acceptable. Another commentor stated that the small quantities of R&D shipments would in themselves indicate the R&D nature of the intended use.

d. *Response.* Since EPA has limited ability to review actual use once pesticides are exported, the Agency must rely on records substantiating the intended use. EPA may

determine that any shipment or series of shipments of an unregistered pesticide, for which small-scale R&D purposes cannot be substantiated, is in violation of the requirements of section 17(a)(2).

EPA believes that examination of appropriate records will be adequate to determine whether small-scale R&D criteria are met. Records to support claims of this nature must contain at least the following information: (1) identify the product and quantity shipped in a given year to a given purchaser in a specified country; (2) include a detailed description of use patterns (i.e., application rates, sites, dosages, etc.) which are consistent with the premise that the shipped quantity would be used within the R&D criteria; and (3) contain confirmation, such as signed statements from the purchaser, letters of transmittal, etc., which indicates that the shipment(s) of the product were to be used for R&D purposes consistent with the quantity shipped and the described uses. EPA does not believe that records which only show the quantity of product shipped are sufficient for substantiating R&D intent, since a quantity that would qualify as "research" for one type of product or use may represent a commercial-sized quantity for a different product or use.

EPA has reconsidered the proposed 3-year duration for record retention and instead is requiring that the records must be retained for the period specified at 40 CFR 169.2(h). This is being done to be consistent with other recordkeeping requirements for these products. At the time of publication of this notice, this period is 2 years.

5. *Timing of Purchaser Acknowledgement Statements.* — a. *1980 policy.* Section 17(a)(2) requires that before exporting a pesticide which is not registered for use in the United States, the purchaser must acknowledge in writing its understanding that the product is not registered for use in the United States and cannot be sold in the United States.

Under EPA's existing policy, an exporter of an unregistered product must have a copy of the signed statement prior to the export of the first shipment each year of an unregistered product to a particular purchaser for each country.

b. *1990 proposal.* In the 1990 proposal, EPA stated that it was examining its policy of requiring annual submissions of the purchaser acknowledgement statement. EPA proposed maintaining the current system of annual submissions, as described above, but also requested comment on the option of requiring purchaser acknowledgement statements for each shipment.

c. *Comments.* Twelve commentors strongly supported maintaining the current system. Most commentors believed that the current system of annual submissions should be continued. They contended that per-shipment notification would create a large paperwork burden, delays in shipment, and trade

disadvantages. One foreign government commented that annual submissions would meet their needs.

One commentor supported per-shipment notifications, or alternatively, the requirement of a detailed annual summary, specifying the quantity shipped and the dates, to show the flow of shipments over the entire year. The commentor suggested that EPA could require the information to be provided at the beginning of the year's shipments and updated if anticipated shipments deviate from the initial projections. The commentor stated that such a notification system has worked reasonably well under the hazardous waste export program pursuant to the Resource, Conservation and Recovery Act (RCRA), and has the significant additional benefit of providing much more useful information to other governments, U.S. agencies, and the public.

Another commentor requested that EPA require exporters to submit the signed statements to EPA within 10 working days of receipt or prior to the first shipment, not within 7 days of receipt as currently required.

d. *Response.* EPA has decided that purchaser acknowledgement statements must be submitted on a per-shipment basis unless the exporter complies with all of the provisions of an alternative approach as provided in this policy. The alternative approach requires the exporter to obtain a purchaser acknowledgement statement prior to the first shipment of each unregistered pesticide to a particular purchaser in a foreign country, and to submit to EPA an annual summary of all shipments of that product to that purchaser.

EPA believes that the Congressional intent underlying the purchaser acknowledgement statement requirement was that countries receive information concerning each shipment of unregistered pesticides to their country. Section 17(a)(2) requires that the foreign purchaser sign a statement acknowledging awareness of the registration status of the product and that the exporter submit this statement to EPA prior to export of an unregistered pesticide. Since section 17(a)(2) specifies that no unregistered pesticide shall be exported without a signed purchaser acknowledgement statement, it is EPA's interpretation that this section requires that there be a purchaser acknowledgement statement for every shipment.

At one time, EPA believed that annual submission of a notice for the first shipment in the calendar year to each purchaser in each country was adequate to meet this requirement, because it would provide regular notification to foreign governments. In the 1980 policy, EPA did not consider per-shipment submissions to be advantageous and therefore exercised its enforcement discretion and allowed one submission per year per purchaser per country for the first shipment. However, EPA agrees with the commentor who stated that per-shipment notifications

would provide useful information. Consequently, EPA is changing its policy to require per-shipment notifications, so that more information about shipments of unregistered pesticides will be available to purchasers and other governments.

EPA recognizes that per-shipment purchaser acknowledgement statements would present a greater burden than the current system. EPA therefore believes that an alternative approach would provide essential information while minimizing the administrative and paperwork burden.

Under the alternative approach, rather than submitting per-shipment purchaser acknowledgement statements, exporters would be permitted to satisfy the purchaser acknowledgement statement requirement as follows. The exporter would submit to EPA a signed purchaser acknowledgement statement for the first shipment each calendar year of an unregistered pesticide to a particular purchaser in a particular country. The exporter would attach to that first purchaser acknowledgement statement sent to EPA, a certification signed by the exporter that export did not take place until a signed acknowledgement statement was received, and provide information which can be used to identify any research and development products (other than those exempt from the purchaser acknowledgement statement requirement, as described at 40 CFR 168.75(b)(2)) referred to by code names in the purchaser acknowledgement statement. In addition, the exporter must include in the signed certification a statement certifying that, for that calendar year, the exporter will submit an annual summary using the procedures detailed in this policy.

Under this alternative approach, the exporter would be required to submit to EPA an annual shipping summary at the end of the year, which summarizes the dates and destinations of all shipments of that pesticide to each particular purchaser exported during the previous calendar year. The annual summary must include the purchaser's name and address, the date of the purchaser's signature in the purchaser acknowledgement statement submitted to EPA during the previous calendar year, the known destinations of the shipment, and the identity of the product and active ingredient(s). The annual summary must be submitted to EPA by March 1st of each year. EPA does not believe the annual summary would be very burdensome because the information should be readily available to exporters in their records of shipments, which they are already required to maintain under 40 CFR 169.2.

EPA will send a copy of the annual shipping summary to the appropriate government officials after it is received.

EPA considered requesting that information on the quantity of pesticides exported be included in the annual summary. EPA believes that while quantity information may be useful in providing more information

about exports, it is not necessary to implement section 17(a)(2). In addition, EPA has concluded that this information may be entitled to protection as confidential business information, as discussed in Unit III.C. of this preamble. For these reasons, and for the reasons discussed in Unit III.B.8 of this preamble (Information Requirements for the Purchaser Acknowledgement Statement), EPA has decided not to require it.

In summary, the section 17(a)(2) requirement for a purchaser acknowledgement statement can be met by exporters complying with either of the following two options: (1) Submit a purchaser acknowledgement statement for each shipment of unregistered pesticides; or (2) submit a purchaser acknowledgement statement for the first shipment each year of a particular pesticide to a particular purchaser for each importing country, including the appropriate certification, and submit a report to EPA which lists the dates and destinations of all shipments exported during the previous calendar year.

The procedures that an exporter of unregistered pesticides must follow in obtaining and transmitting the foreign purchaser acknowledgement statements are set forth in 40 CFR 168.75.

*e. Effective date for 40 CFR 168.75.* Under both the per-shipment option and the annual reporting option for complying with section 17(a)(2), the schedule for obtaining and transmitting purchaser acknowledgement statements is based on the calendar year. However, because this policy has been published several months into a new calendar year, exporters may have already sent EPA purchaser acknowledgement statements under the provisions of EPA's 1980 Pesticide Export Policy. In order to facilitate compliance with this policy, the effective date for the new purchaser acknowledgement statement requirements is June 1, 1993. Thus, all the requirements of 40 CFR 168.75 will be applicable as if June 1 was the start of the 1993 calendar year. Beginning June 1, 1993, exporters must submit purchaser acknowledgement statements on a per-shipment basis, unless the exporter complies with the provisions of the alternative approach of annual reporting procedures as provided in this policy. Under the per-shipment approach, the exporter will have to obtain, prior to each shipment of an unregistered pesticide product to a country, a signed purchaser acknowledgement statement, in accordance with 40 CFR 168.75(c)(2)(i). The exporter must submit the signed purchaser acknowledgement statement to EPA in accordance with the requirements of this policy.

If the exporter chooses the annual reporting procedures, he or she must comply with all the requirements specified in 40 CFR 168.75(c)(2)(ii) effective June 1, 1993. The exporter must obtain, prior to the first shipment occurring after June 1, 1993, of an

unregistered pesticide product to a particular purchaser in a country, a signed purchaser acknowledgement statement in accordance with 40 CFR 168.75(c)(2)(ii).

In addition to the purchaser acknowledgement statement for the first shipment, the exporter must submit a certification that he or she is choosing the annual summary compliance option. The exporter must submit the signed purchaser acknowledgement statement and certification in accordance with the requirements of this policy. In March 1994, the exporter choosing the annual reporting option for the June 1, 1993 through the December 31, 1993 period must submit to EPA a summary of shipments of each pesticide to each purchaser sent during that period.

In subsequent years, the period for exporters choosing the annual reporting option will be the calendar year. (Purchaser acknowledgement statements submitted to EPA during the period January 1, 1992 through May 31, 1993, will be governed by the policy published in 1980 (45 FR 50274, July 28, 1980).

*6. EPA's transmittal of purchaser acknowledgement statements. — a. 1980 policy.* The 1980 policy did not discuss EPA's transmittal of purchaser acknowledgement statements. Under that policy, EPA sent copies of the purchaser acknowledgement statement to the Department of State. Along with the purchaser acknowledgement statement, EPA sent a cover sheet which identified the registration status of the pesticide. (The status is identified as: not registered; denied registration; canceled; or registration status unknown.) The State Department then transmitted the purchaser acknowledgement statement with EPA's cover sheet, to the U.S. diplomatic post in the importing country, which in turn sent it to an appropriate government official in that country.

*b. 1990 proposal.* EPA proposed sending purchaser acknowledgement statements directly from EPA to officials in importing countries, and if different, the country or countries of final destination, if known.

*c. Comments.* All commentors supported the idea of direct transmittal of purchaser acknowledgement statements to foreign governments, citing improved timeliness and efficiency.

*d. Response.* EPA intends to implement this approach and has made arrangements to do so. These notices will, therefore, be transmitted directly by EPA to appropriate officials of the country of import and, where reported, to the countries of final destination or intended use. EPA will also send a copy of the annual shipping summary, as discussed in the response to the previous comment, to the appropriate officials after it is received.

EPA has decided that the appropriate governmental official to receive section 17(a) notifications will be the person named as the designated national authority (DNA) for

pesticide notifications in the international prior informed consent program (PIC). The DNA has the responsibility for both receiving and disseminating information associated with the PIC procedures. Countries may participate in PIC as either an importing country or an exporting country. Exporting countries are expected to participate in PIC for the purposes of participating in information exchange procedures and export control features. For countries which are not participating in PIC, EPA will ascertain the names of the appropriate persons to receive the section 17(a) notifications.

**7. Format of the purchaser acknowledgement statement.—a. 1980 policy.** The 1980 policy set forth a recommended content for purchaser acknowledgement statements, but did not recommend or require a specific format.

**b. 1990 proposal.** The Agency solicited comments on whether the purchaser acknowledgement statement would be more useful if a specific format were required, or if a particular form were provided, e.g., a form similar to the accepted international form for notification under the PIC program.

**c. Comments.** Nine commentors supported the idea of a standardized format. Four industry commentors expressed strong reservations with using a form or format that closely resembles PIC notification forms for banned or severely restricted pesticides. They pointed out that not all unregistered products are banned or severely restricted and that using a form that closely resembled the PIC notification for banned or severely restricted chemicals would be confusing and misleading. Two commentors suggested following a format designated by FAO/UNEP as the basis for a standardized format for the purchaser acknowledgement statement.

**d. Response.** EPA believes that standardization of purchaser acknowledgement statements would improve the consistency of submitted information and the familiarity of foreign governments with a given format thus expediting review and reducing misunderstandings. Purchaser acknowledgement statements vary greatly in quality and content. Many do not adequately identify the pesticide being shipped or the country of the purchaser. Even though this information is currently required, the lack of a standardized format may make compliance more difficult. EPA believes that a specific format will facilitate compliance, improve information transmittal from exporters, and strengthen the Agency's ability to manage the information contained in purchaser acknowledgement statements.

One of the reasons EPA is considering a format or form for the purchaser acknowledgement statement is to improve the utility of the information provided by the purchaser acknowledgement statements to foreign governments. The Agency agrees with those commentors who suggested that it would be misleading for the form or format

to closely resemble another form which transmits different information. Any forms and/or format which EPA may develop will be reviewed to assure that they cannot be mistaken for PIC notification forms dealing with banned or severely restricted chemicals.

EPA is considering developing and making available purchaser acknowledgement forms in different languages. EPA believes that multilingual purchaser acknowledgement statements would ensure that the documents could be understood by the widest possible audience. If these forms are developed, it is EPA's intent that they will be published in the Federal Register for comment. Until the forms are available, any format that is clearly understandable and includes the required information is acceptable. In the interim, EPA plans to provide a cover sheet in French, English or Spanish (the official languages of the PIC system) with each purchaser acknowledgement statement EPA transmits to importing governments. EPA believes that cover sheets in the appropriate language will aid countries in understanding and using the information in the purchaser acknowledgement statement.

**8. Information requirements for the purchaser acknowledgement statement.—a. 1980 policy.** In EPA's 1980 Policy, the Agency stated that the purchaser acknowledgement statement must include the following information:

- (1) The exporter's name and address.
- (2) The foreign purchaser's name and address.
- (3) The name of the product and the active ingredient.
- (4) An indication that the purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States.
- (5) The destination of the export shipment if different from the purchaser's address.
- (6) The foreign purchaser's signature.
- (7) The date of the signature.

**b. 1990 proposal.** EPA proposed that more information be provided in purchaser acknowledgement statements. Specifically, EPA proposed that the country or countries of final destination be identified in the purchaser acknowledgement statement, so that EPA could begin to send these notices directly to the regulatory officials in these countries. In some instances, this would represent a broadening of the requirement in the 1980 policy, which only required "the destination" of the shipment to be included.

**c. Comments.** There were only a few comments specifically addressing this issue. One commentor supported the proposed expansion to include the country of final destination, while another commentor proposed that the purchaser acknowledgement statements be expanded to include information about the quantity and frequency of the shipments. Commentors from both industry and other governments stated that the country of final destination will often not be

known by the exporter at the time of shipment.

**d. Response.** EPA considered other information which could be included in a purchaser acknowledgement statement in order to make the notifications clearer and more useful to other governments. EPA is requiring, as part of this final policy, that exporters provide the Chemical Abstracts Service (CAS) registry number for each active ingredient in a product, the International Union of Pure and Applied Chemists (IUPAC) chemical name for each active ingredient, and other known chemical or common names by which the product is known. The Agency believes this information is necessary for adequate identification of the product and active ingredients. In addition, the identity of the country of final destination should be included in the purchaser acknowledgement statement, to the extent this information is known to, or reasonably ascertainable by, the exporter.

On April 25, 1991, EPA issued a class determination finding that the identity of the country of final destination is not entitled to confidential treatment. A copy of the class determination is reprinted in Unit III.C. of this preamble.

EPA acknowledges that the country of final destination may not be known by the exporter at the time of shipment. As with requirements regarding multilingual language on labels, this requirement is contingent on the exporter having actual knowledge of the country of final destination, or if it can be determined that the information was reasonably ascertainable to the exporter.

In response to the comment received, EPA considered requiring information about the quantity of shipments in purchaser acknowledgement statements. EPA agrees that information about the quantity of unregistered pesticides exported would be useful to other countries, to EPA and to other agencies, and in responding to inquiries from Congress and the public. Information about the quantity of pesticides shipped would give importing countries valuable information for regulating pesticide use in their countries. However, EPA's authority to require quantity information under FIFRA section 17(a)(2) is subject to question and requiring this information could create difficulties in protecting confidential business information from release as required by FIFRA. Therefore, EPA will not require quantity information to be included in the purchaser acknowledgement statements.

**9. Language requirements for purchaser acknowledgement statements.—a. 1980 policy.** The 1980 policy did not contain any language requirements for the exporter to meet to satisfy the purchaser acknowledgement statement requirement of section 17(a)(2).

**b. 1990 proposal.** EPA proposed requiring that purchaser acknowledgement statements be written in English, the language of the



purchaser's country, and the languages of the country or countries of final destination. In the case where more than one language is involved because the product is shipped to more than one destination, EPA proposed that the exporter must submit either a multilingual statement to EPA, or multiple statements in all required languages. EPA believed that these changes would assist the purchasers and the importing governments in understanding the contents and significance of the purchaser acknowledgement statements.

c. *Comments.* EPA received many comments on its proposal to make the purchaser acknowledgement statement multilingual. Four governments and the OECD representative supported the proposal, although the latter wondered how EPA would know all of the intended destinations and hence required languages. One environmental group and one industry commentator also supported the proposal.

Most of the commentators from industry objected to the proposal that purchaser acknowledgement statements be multilingual, and some objected to the minimal bilingual proposal as well. Many of the arguments were identical to those raised regarding the proposal that labeling be multilingual. (See 55 FR 4971.) For example, it was pointed out that the country of final destination would not always be known as in the case of an active ingredient exported for reformulation. One commentator stated that the burden of translating the purchaser acknowledgement statements might be disproportionately high on small businesses who may not have multilingual or bilingual staff. Another stated that a foreign purchaser may be reluctant to sign a statement which included language which the purchaser cannot read. This commentator believed that the requirement of multilingual or bilingual purchaser acknowledgement statement would in practice require foreign purchasers to be adept in all of the languages on the purchaser acknowledgement statement. Most of the industry commentators did not object to the minimal proposed bilingual requirement.

d. *Response.* EPA believes that multilingual purchaser acknowledgement statements would be very useful in communicating necessary information as evidenced by the support for this proposal from foreign governments. However, the numerous comments raised by industry indicate that there are practical problems which need to be addressed. EPA also recognizes that requiring exporters to translate purchaser acknowledgement statements into different languages would place a new burden on industry, particularly small businesses. As noted earlier, EPA is considering developing forms for exporters to use as purchaser acknowledgement statements which are already in different languages. The forms could be developed in English, French, and Spanish, which are the official languages of the PIC program. EPA believes that this

approach would be more efficient than requiring each exporter to develop its own multilingual purchaser acknowledgement statements. Due to the number of practical problems to be worked out, EPA does not have such forms at this time, and EPA is considering publication of a proposal on this issue at a later date.

As discussed above in Unit III.B.7. on format of the purchaser acknowledgement statement, until multilingual purchaser acknowledgement statement forms can be developed, EPA plans to include a cover sheet in the appropriate language with each purchaser acknowledgement statement the Agency transmits. There will be no requirement for the purchaser acknowledgement statement to be in multiple languages at this time. However, if the foreign purchaser signs a purchaser acknowledgement statement in their own language, it must be accompanied by an English translation when it is submitted to EPA by the exporter.

### C. Confidentiality

1. *Information treated as confidential.—a. 1980 policy.* EPA's 1980 policy statement permitted exporters to claim all the information required in the purchaser acknowledgement statement as trade secrets or confidential business information (CBI). In the past, and in accordance with its 1980 policy statement, EPA treated information submitted in purchaser acknowledgement statements as confidential within the meaning of its regulations on business confidentiality at 40 CFR part 2, subpart B, when such information had been claimed confidential by the exporter.

b. *January 12, 1990 policy statement.* In the Federal Register Notice regarding the confidentiality of certain information submitted under sections 7 and 17(a)(2) of FIFRA, dated January 12, 1990 (55 FR 1261), EPA clarified that section 7(d) of FIFRA excludes the names of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment, from protection as confidential business information. In addition, EPA stated that the names of producers of unregistered pesticides are a matter of public record under FIFRA section 4. The notice also explained that since unregistered pesticides generally may be manufactured only for the export market, the fact that a company has submitted a purchaser acknowledgement statement to EPA under section 17(a)(2) for a given pesticide could therefore be determined from public information. Accordingly, the identity of the producer of the unregistered pesticide product, and if applicable, the name of the active ingredient would no longer be accorded confidential treatment by EPA.

c. *Comments and response.* Several commentators in response to the January 12, 1990 notice stated that no information in a purchaser acknowledgement statement should

be confidential, asserting that the information was readily accessible to interested parties either in published reports or upon request.

d. *1990 proposal.* The proposed policy on section 17(a) clarified that certain information contained in purchaser acknowledgement statements will not be entitled to confidential treatment. Specifically, the proposed policy clarified that the name and address of the exporter, and the name of the product and the active ingredient will not be considered confidential. In addition, EPA proposed to issue a class determination under 40 CFR 2.207 concerning the confidentiality of country of final destination as reported on purchaser acknowledgement statements. EPA also requested comment on whether a similar determination should be made for information identifying the foreign purchaser.

e. *Comments.* Several commentators stated that disclosure of the country of import and the country of destination, coupled with the non-confidential name of the exported product would be an unfair public disclosure of a company's marketing position. They stated that this would provide an unfair advantage to foreign-based competitors. Some commentators explained in detail the public sources for this information. They explained that the cost of obtaining the information from other sources would not be prohibitively high for well-financed exporters. Exporters stated that while public sources of the information existed, they were not as accurate or as detailed as the information which EPA would make available, should the information be deemed non-confidential.

f. *Response.* EPA's research and inquiries suggest that destination information is generally already a matter of public record. Some countries publish lists identifying monthly pesticide imports, including information on the name or type of pesticide, the exporting company, and the exporting country. Other countries make this information available on request. Information on international markets for particular pesticides is widely available through advertising by U.S. exporters.

In addition, compilations exist which list pesticides and their regulatory status throughout the world, such as volumes published jointly by the Agricultural Requisites Scheme for Asia and the Pacific and the International Cooperation Center for Agricultural Research and Development. Private publishers provide information on pesticide exports at a substantial cost. Battelle publishes "World Pesticide Programs" reports which provide detailed information on pesticide use in foreign countries. "Agrow World Crop Protection News" offers market planning and development information and lists pesticides registered in various countries. The Port Import/Export Reporting Service (PIERS) database of the Journal of Commerce provides information on all shipments leaving the United States. Information available to customers of PIERS

includes commodity exported (although the precise identity of the pesticide may not be given), manufacturer or shipper, destination and estimated quantity.

In addition to the availability of destination information in many public sources, EPA believes that treating the country of destination as non-confidential would have public health and environmental benefits. EPA intends to send copies of the purchaser acknowledgement statements to all the countries of destination identified by the exporters on the statement. Information that particular pesticides are being shipped to their country should provide countries with information useful in monitoring and controlling imported pesticides.

One commentator stated that information on quantities shipped should not be confidential. The 1980 policy did not require information on the quantity of pesticides exported to be submitted as part of the purchaser acknowledgement statement. EPA considered requiring information on quantity in the purchaser acknowledgement statement, and treating this information as non-confidential. Many companies objected to the disclosure of any information on the quantity of pesticide exported. Several companies were concerned that information about quantity sold would substantially harm their companies' competitive positions by revealing information about their market share. These companies claim that any public data about quantity is either estimated or in obscure sources and not currently available in a form that would provide the significant advantage to competitors that EPA's reports would provide.

After research and analysis of this issue, EPA has concluded that while quantity information may be useful in providing more information about exports, it is not necessary to implement section 17(a)(2).

EPA also requested comment on whether a similar determination should be made for information identifying the foreign purchaser. The name and address of the foreign purchaser may be entitled to confidential treatment if it reveals information about the customer list of the pesticide company. However, if the foreign purchaser is merely a distributor for the pesticide company in the foreign country, then this information would not generally be considered privileged.

Several groups commented that there should be no confidential information in a purchaser acknowledgement statement. They claimed that this information may be publicly available or estimated in international trade magazines or other services. EPA believes that companies have a valid interest in protecting information which could divulge their customers or marketing strategies, and thus not all information in a purchaser acknowledgement statement should be treated as non-confidential. One commentator stated that only financial information should be protected as confidential. EPA believes that

this is too narrow an interpretation. For example, courts have held that any information that could reveal market share is confidential business information.

Many commentators were concerned about the release of any information on research and development products. Companies indicated that confidentiality would be essential for such shipments to avoid revealing information which could be invaluable to competitors. These commentators stated that information about R&D products including the chemical identity of the research product, the quantity being shipped, the potential use pattern, and the country of final destination should be confidential. Several exporters explained that new products are often developed simultaneously in different countries before the patent status of new research materials has been settled. Most countries, unlike the United States, have a first-to-file patent law, not a first-event law. This means that the identity of an unpatented research compound could be patented without proving that the filer discovered the compound first. Therefore, premature release of R&D information could jeopardize the U.S. producer's patent rights to a new product. Companies also commented that public disclosure would allow competitors to learn about the new areas of chemistry being explored by the exporter. Competitors could explore these new areas and compromise the exporter's competitive advantage in research.

Other commentators stated that R&D information relevant to public health and the environment should not be withheld from the public in the country of import or the public in the United States.

**2. Confidentiality of R&D information.** EPA believes that companies' concerns that the premature release of information about research and development products may lead to a potential loss of patent rights are valid concerns. Therefore, EPA has concluded that information about research and development products is generally entitled to confidential treatment.

**3. Class determination.** Based on the considerations discussed above, and in accordance with its regulations at 40 CFR 2.207, on April 25, 1991, EPA issued a Class Determination (1-91, Identity of Importing Country Under FIFRA section 17(a)(2)), concluding that information on the identity of the importing country, reported to EPA in purchaser acknowledgement statements, is not entitled to confidential treatment under 5 U.S.C. 552(b)(4) of the Freedom of Information Act or FIFRA. The effect of a class determination is to make known the Agency's position regarding the manner in which information within the class will be treated in accordance with the provisions of EPA's confidentiality regulations. Publication of this class determination is not sufficient grounds to release information claimed confidential since both 40 CFR 2.204(e)(1) and 40 CFR 2.205(f)(2) require that before

release of information claimed to be confidential, notice must be given by certified mail or by other means by which the date of receipt of the notice can be verified.

Any companies who have previously claimed information about the destination of their export shipments to be confidential, will receive the notice provided for in EPA's regulations before the Agency releases this information. (40 CFR 2.204(d)(2) or 40 CFR 2.205(f)).

Persons submitting the information specified in the purchaser acknowledgement statement may assert a claim of business confidentiality by marking the information claimed confidential as "FIFRA Confidential Business Information." Information so claimed will not be disclosed, with the exception of disclosure to the foreign governments, except in accordance with the procedures set forth in 40 CFR part 2, 7 U.S.C. 136(h), and this policy statement. Notwithstanding any claim of confidentiality, the purchaser acknowledgement statement will continue to be forwarded to the appropriate foreign government officials in its entirety, as required by section 17(a)(2).

In summary, the following information will generally not be considered confidential: (a) The fact that a producer makes a registered or unregistered pesticide product; (b) the fact that an acknowledgement statement or other notice of export has been filed by an exporter; (c) the identity of the unregistered exported product; and, if applicable, the identity of the active ingredients of the pesticide; and (d) the identity of the importing country and the country or countries of final destination, if known. Information subject to the following class determination 1-91 will not be considered confidential and claims of confidentiality for this information will be denied.

#### Class Determination 1-91

#### Identity of Importing Country Under FIFRA Section 17(A)(2)

##### 1. Background

Section 17(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) sets out the conditions under which pesticides not registered for use in the United States may be exported to other countries. Under that provision and the Environmental Protection Agency (EPA) statement of policy governing its implementation (45 FR 50274, July 28, 1980), a pesticide which is not registered under section 3 or sold under section 6(a)(1) of FIFRA may be exported only if, prior to export, (1) the foreign purchaser signs a statement acknowledging it understands that the pesticide is unregistered and cannot be sold in the United States and (2) a copy of the acknowledgement statement has been transmitted to EPA for sending to the government of the importing country. Under EPA's policy, these requirements apply only to the first shipment of each unregistered pesticide to a particular purchaser in a given country annually.

EPA's 1980 policy statement permitted exporters to claim as confidential business information required to be reported to EPA on the foreign

purchaser's acknowledgment statement. The information required to be reported is as follows:

- (a) Name and address of the exporter;
- (b) Name and address of the foreign purchaser;
- (c) Name of the product and the active ingredient and an indication that the purchaser understands that the product is not registered for use in the United States;
- (d) Destination of the export shipment if different than purchaser's address;
- (e) Signature of the foreign purchaser; and
- (f) Date of the foreign purchaser's signature.

In the past, and in accordance with that policy statement, EPA has treated this information as confidential when so claimed by the exporter. However, EPA issued another policy statement on January 12, 1990 (55 FR 1261) addressing the confidential status of information reported to EPA under section 7 of FIFRA which necessarily affected the confidentiality of certain information reported under section 17(a)(2).

Specifically, because section 7 mandates that certain information is not entitled to confidential treatment, the fact that a company has submitted a notice under section 17(a)(2) for a given pesticide is necessarily public as well. (The active ingredient of that pesticide is also public information).

This class determination addresses the confidentiality of the identity of the importing country of the unregistered pesticide export. It does not address the status of information about the foreign purchaser, information reported about research and development products, or quantity of shipment information which may be recorded on the purchaser acknowledgment statement.

## II. Findings

Under EPA's regulations on business confidentiality at 40 CFR 2.207, I have authority to issue class determinations concerning entitlement of business information to confidential treatment. In the case of the information reported to EPA under FIFRA section 17(a)(2) concerning the identity of importing country I have found:

- (1) EPA possesses numerous notices filed under FIFRA section 17(a)(2) and will continue to receive such notices in the future.
- (2) The information reported concerning importing country is of the same nature and therefore can be treated similarly for the purpose of this determination.
- (3) A class determination will serve a useful purpose by simplifying EPA responses to Freedom of Information Act (FOIA) requests for information contained in the notices, reducing the burden of individual determinations and informing requesters and affected businesses of EPA's position in advance.

EPA may withhold information from disclosure under the FOIA if the information falls within one of the exemptions in the Act. One exemption is for "trade secrets" and commercial or financial information obtained from a person and privileged or confidential. 5 U.S.C. 552(b)(4). The matter to be decided in this class determination is whether the identities of importing countries reported under FIFRA section 17(a)(2) are entitled to be withheld from disclosure under this exemption of the FOIA.

The information in question is clearly commercial information obtained from a person. The issue is whether this information is trade secret or otherwise confidential within the meaning of 5 U.S.C. 552(b)(4) and EPA's business confidentiality regulations at 40 CFR part 2, Subpart B.

Before EPA may conclude that information is exempt from disclosure as trade secret or

confidential commercial information, the Agency must find that the information is in fact maintained in confidence by the business and is not publicly available. If it is not maintained in confidence or is publicly available, it is not entitled to confidential treatment and EPA must disclose the information.

The weight of evidence shows that destination information on unregistered pesticides is publicly available for many such exports. For example, some countries publish lists identifying monthly imports including information on the name or type of pesticide, the exporting country and the exporting company. Other countries make this information available on request.

Also widely available is information on international markets for particular pesticides. There is widespread advertising by United States exporters on billboards and in stores in foreign countries for pesticides sold in those countries but not registered in the United States. Similar advertising appears in domestic and foreign publications.

There also exist compilations listing pesticides and their regulatory status throughout the world, such as three volumes published jointly by the Agricultural Requisites Scheme for Asia and the Pacific and the International Co-operation Centre for Agricultural Research and Development covering Asia, the Pacific, and Africa.

In addition, considerable information on destination of pesticide exports is available from private publishers at a cost which is high but not prohibitively so for pesticide manufacturers. For example, Battelle publishes "World Pesticide Programme" reports which provide detailed information on pesticide use in foreign countries. "Agrow World Crop Protection News" offers market planning and development information and lists pesticides registered in various countries.

Finally, the Port Import/Export Reporting Service (PIERS) database of the Journal of Commerce provides information on all shipments leaving the United States. Information available to customers of PIERS varies in the level of detail provided, but may include commodity exported, manufacturer or shipper, destination and quantity.

Therefore, it appears that in many instances destination information on unregistered pesticide exports is not maintained in confidence and is in fact available to the public. For those exports, destination information is not entitled to confidential treatment by EPA. Since this determination must cover all notices received under section 17(a)(2), however, it is necessary to continue the confidentiality analysis to apply to those exports for which destination information may in fact be held in confidence.

Information that has been kept in confidence may be entitled to confidential treatment under 5 U.S.C. 552(b)(4) if it meets one of the tests set out in *National Parks Conservation Association v. Morton*, 498 F.2d 765 (D.C. Cir. 1974). Under *Morton*, commercial or financial information may be withheld from disclosure if revealing the information would be likely (1) to impair the ability of the government to obtain necessary information in the future or (2) to cause substantial harm to the competitive position of the submitter of the information.

The first test is not applicable to export destination information because such information is required to be submitted to EPA under FIFRA 17(a)(2) and EPA's policy statement. Therefore, the information is not voluntarily submitted and EPA's ability to obtain it in the future would not be

impaired by disclosure. Accordingly, the applicable *Morton* test is the second one, whether disclosure of this information would be likely to cause substantial harm to the competitive position of the submitter.

Country of destination information other than information concerning pesticides in the research and development stage is not the type of information that would likely cause substantial competitive harm to a submitter if it were released. If not coupled with information about quantity shipped, the identity of the country of destination does not reveal specific information about the company's customer list or market share. While an argument can be made that releasing information concerning research products could enable competitors to learn new areas of chemistry being explored by the exporter and thwart "first to file" patent laws, no similar argument can be made for pesticides in an established market. Therefore, under the second *Morton* test, information identifying the country of destination of unregistered pesticide exports is not entitled to confidential treatment.

## III. Conclusion

For the foregoing reasons, I find that information reported to EPA under FIFRA section 17(a)(2) on unregistered pesticide exports identifying the importing country is not entitled to confidential treatment under 5 U.S.C. 552(b)(4) or FIFRA. Date April 25, 1991.

Craig B. Amear  
Associate General Counsel

## D. FIFRA Section 17(b) Notification Programs

1. *Background.* — a. *EPA's 1975 notice.* In 1975, EPA issued a Federal Register notice interpreting the section 17(b) international notification requirement to apply to "information having international significance." (40 FR 20987, May 14, 1975). In that notice, EPA indicated that notices to foreign governments would be sent under two conditions: (1) whenever the Agency registers, under the authority of section 3, a pesticide that contains any new active ingredient or entails a new use, and (2) when cancellation or suspension of a pesticide becomes effective and is determined to be of international significance. In the latter instances, EPA indicated that such determinations would be made by applying general guidance on a case-by-case basis.

In the 1975 notice, EPA also indicated what types of action would be considered to be of international significance:

1. Actions resulting from a review of the pesticide; actions resulting from findings of risk.
2. Actions resulting from decisions to reduce or revoke tolerances under the FFDCA.
3. Actions involving issuance of a new policy applicable to the entire pesticide industry.

4. Actions which may have widespread environmental, economic or political implications.

b. *Current practice.* EPA has generally limited section 17(b) notices to cancellations

or suspensions undertaken for health or environmental reasons, and for selected actions which place significant restrictions on a pesticide's use, usually at the conclusion of a Special Review. The section 17(b) notices, as currently designed, discuss in general the health or environmental concerns which prompted the action, and offer to provide additional information upon request. The notices are fairly brief, about three pages in length, and are written in terms easily understood by people who may not be familiar with the U.S. pesticide regulatory program or laws.

Under the current system, EPA's Office of Pesticide Programs prepares a notice and sends it to the Department of State for transmittal to other governments. The State Department transmits a cable to all diplomatic posts, directing embassies to inform the host government of the information in the cable. The embassy then contacts an appropriate government office in the host country and informs the office of the information contained in the cable. Each embassy may handle the notification differently, depending upon individual circumstances. Some notify the Environment Ministry, some inform the Agricultural Ministry, while others may inform the Foreign Ministry which then in turn is expected to inform the pesticide regulatory body. Some embassies may simply provide a copy of the cable, some may set up a meeting to discuss the notice, while others may prepare a formal diplomatic communique to transmit the information.

**c. EPA's goals.** EPA wants to ensure that other governments have information on regulatory actions taken on the basis of public health or environmental concerns involving a pesticide's use. Such information can assist other governments in making informed decisions on the continued use of pesticides in their own countries. EPA believes that providing increased information on pesticide regulatory actions will also help further health and environmental protection goals worldwide. EPA also believes that informing other governments will assist with efforts toward international harmonization, as information about EPA's pesticide regulatory activities may prompt similar actions abroad.

EPA has reviewed the section 17(b) notification program to determine how it fits in with EPA's international goals. EPA wants to inform foreign growers of any U.S. pesticide regulatory action which may affect their ability to export food legally to the United States. If the United States informs other governments of the regulatory actions that the United States has taken with respect to pesticides, those governments may use that information to inform exporting producers or to regulate the application of pesticides on crops destined for export to the United States.

EPA has determined that revisions to its international notification system are warranted. Revisions to the final policy focus on the following areas: The scope of the

international section 17(b) transmittals; the frequency of such transmittals and the content of the notifications; and the transmittal process itself. These areas are discussed in greater detail below.

**d. 1990 proposal.** EPA requested comment on proposed revisions to its policy on notification of foreign governments of certain types of pesticide regulatory actions. FIFRA section 17(b) requires international notifications whenever a registration, cancellation, or suspension of a pesticide's registration becomes effective, or ceases to be effective. Since a major objective of EPA's review of its section 17(b) policy was to improve the utility of the notification process to recipients, EPA sent copies of the proposal out for comment to foreign countries and international organizations.

EPA proposed to broaden the scope of section 17(b) notifications to include all actions taken on the basis of health or environmental concerns, to increase the frequency and to amend the transmittal process for the notifications.

**1. Scope of section 17(b) notification program.** EPA proposed to expand the scope of actions subject to international notification to include all regulatory actions taken on the basis of health and environmental criteria so that countries receive important information about pesticide risks. EPA also proposed that countries should be notified of all major actions which affect pesticide use, including actions which eliminate all registrations for an active ingredient or substantially change a pesticide tolerance.

**a. Types of regulatory decisions.** Every year, EPA takes thousands of different types of regulatory actions affecting pesticide products. These actions encompass routine, noncontroversial decisions, as well as regulatory actions that involve highly contentious issues, and those which address serious concerns about public health and environmental risks. EPA considered a number of factors in determining which regulatory actions should be subject to the notification requirement, and in determining how the information should be transmitted. Among the factors to be considered are: statutory requirements; EPA's policy goals for international pesticide efforts; consistency with international activities; the value of the information to the recipient; and competing demands on EPA's and other agencies' resources.

**b. Legislative mandate.** A literal reading of section 17(b) (see Unit II.B.2 of this preamble) could require thousands of notifications annually: every time EPA amends a registration; cancels a registration for failure to pay maintenance fees; or cancels a registration at the request of a registrant. EPA believes that this requirement should be interpreted consistent with the intent of Congress to provide meaningful information to other countries (S. Rept. No. 92-1540, 92nd Cong. 2d Sess. at 33 (1972)).

In the 1975 Notice, EPA noted that the legislative history of section 17(b) indicates that notices should serve a useful purpose. EPA went on to conclude that it would not serve a useful purpose to transmit notices for all of the actions which could conceivably fall within the scope of this requirement, and in fact, that notification of routine actions would likely lessen the impact of information having international significance. This interpretation has guided EPA in its decisions to transmit notices.

In the February 1990 Federal Register notice, EPA proposed that section 17(b) notices should encompass all actions taken on the basis of health or environmental considerations. EPA also proposed that section 17(b) should encompass all major actions which affect pesticide use. This would include actions affecting foreign growers who wish to export food to the United States.

**c. Comments.** All commentors on this issue supported expanding the scope of actions subject to section 17(b) notifications. Two commentors supported the scope of actions for section 17(b) actions as proposed, including an annual summary of the actions that meet EPA's criteria. Two commentors suggested sending notices for all new registrations. Another commentor suggested sending notices for all partial cancellations and suspensions. Three commentors supported sending notices on those pesticides withdrawn from the market for other than health or environmental reasons.

**d. Response.** EPA proposed that section 17(b) notices should be sent for proposed and final suspensions and cancellations taken as a result of the pesticide's potential to cause unreasonable adverse effects (FIFRA sections 6(b) and 6(c)). EPA believes that information about final actions taken on the basis of health and environmental criteria would be the most critical for timely international notifications and will continue to send such notices under section 17(b).

However, EPA will continue to advise other nations about major proposed actions so that they will be aware of emerging health and safety concerns, and will have an opportunity to participate in the regulatory process. These notices allow other countries an opportunity to participate in our decisions, and they set an example we are encouraging other countries to follow. Moreover, sending these notices would be consistent with the U.S. negotiating positions in the General Agreement on Tariffs and Trade (GATT) and the North American Free Trade Agreement (NAFTA), and such notifications would be required once these agreements are adopted.

Partial cancellations or suspensions which occur for administrative reasons, e.g., failure of the registrant to pay the fee required would not impart particularly significant information to the recipients of the notices. However, because this information may still be of interest to other countries, a summary of all pesticide regulatory actions will be sent

annually, including the actions for which no section 17(b) notices would be prepared on a routine basis, as described in this section.

EPA has decided to expand the scope of actions which will trigger section 17(b) notifications, to include a general category of other actions which EPA determines to be of international significance. This addition is designed to provide the Agency with the flexibility to report on any regulatory actions which may not clearly fit into other categories on the list of actions triggering a section 17(b) notice, as listed below.

(1) Final suspensions/cancellations as a result of the potential to cause unreasonable adverse effects (sections 6(b) and 6(c)).

(2) Denial of a tolerance following a formal finding that the tolerance does not meet the statutory safety standard.

(3) Denial of an application to register a pesticide product following a formal finding that the risks outweigh the benefits.

(4) Voluntary cancellations of a registration where there is evidence of health or environmental concerns (section 6(f)).

(5) Voluntary withdrawals of registration applications, registrations, or tolerance petitions, where there is evidence of health or environmental problems prior to the withdrawal.

(6) Reregistration actions—issuance of a reregistration eligibility decision document (section 4(g)(2)).

(7) Final actions to establish a new tolerance or exemption from a tolerance, to revoke a tolerance or exemption, or to amend a tolerance.

(8) All registrations of a new active ingredient and (if different) the first food use registration of an active ingredient.

(9) All other actions which eliminate all or virtually all significant registrations for an active ingredient including:

(i) Final cancellations for failure of a registrant to meet conditions of registration.

(ii) Voluntary cancellations.

(iii) Cancellations for failure to pay the fee required to reregister or maintain registration.

(iv) Cancellations resulting from other activity under FIFRA section 4.

(12) Any other pesticide regulatory actions which EPA deems to be of international significance.

No section 17(b) notices would be prepared on a routine basis for the following actions. However, these actions will still be included in the annual summary of pesticide regulatory actions.

(1) Registrations of new uses of a pesticide.

(2) Registration of new products with uses similar to existing registered uses (known as "me-too" registrations).

(3) Suspensions for failure to submit data under FIFRA section 3(c)(2)(B) that do not result in the elimination of all or virtually all uses of an active ingredient.

(4) Cancellation/suspensions that do not result in elimination of the registration of all or virtually all uses of the active ingredient

or are not taken for health and environmental reasons (e.g., voluntary cancellation of a product by a company because of insufficient funds or unwillingness to meet data requirements for reregistration.)

(5) Voluntary withdrawals of petitions for tolerances within 75 days after receipt of a notification from EPA of deficiencies in the data required to support the petition. (See EPA's notice of policy concerning abandoned and incomplete pesticide petitions for tolerances or food and feed additive petitions, 56 FR 43759 (September 4, 1991).)

**2. Timing and frequency of section 17(b) notifications.**—(a) *1990 Proposal.* EPA proposed that the timing of section 17(b) notices should depend upon the potential effect of the action taken. Notifications of regulatory actions based on health and/or environmental concerns should be transmitted as soon as possible after such actions are taken. The Agency also proposed to send an annual summary of pesticide regulatory actions taken during the year.

(b) *Comments.* Ten commentors supported the option EPA proposed to transmit notices of urgent health and environment concerns immediately and to prepare an annual report summarizing these notices and listing less urgent actions taken during the year. One commentor supported maintaining the current system of sending section 17(b) notices as soon as possible after the action occurs.

(c) *Response.* EPA will prioritize the section 17(b) notices to ensure that those dealing with significant health and/or environmental concerns are transmitted immediately. The Agency will also prepare an annual summary of all pesticide regulatory actions and transmit it to countries. The annual summary will list pesticide regulatory actions published in the Federal Register during the year.

### 3. Transmittal of section 17(b) notices.

(a) *Current practice.* EPA transmits both section 17(a) and section 17(b) notices through the State Department. The section 17(a) notices are sent by the State Department to the appropriate embassy for the country of import. The State Department also sends copies of section 17(b) notices to all embassies for delivery to contacts within each country. FIFRA section 17(b) provides that EPA shall transmit section 17(b) notifications through the State Department.

The current practice of transmittal has proved to be a timeconsuming and somewhat inefficient process. The State Department orders all the cables it transmits in terms of priority. Information about domestic regulatory actions is usually of a lower priority than diplomatic activities. Further, embassies may lack sufficient staff to forward the notices quickly to the appropriate government officials in the receiving countries. The current process often delays receipt by foreign governments of information about U.S. pesticide actions.

(b) *1990 proposal.* The Agency proposed to transmit section 17(b) notices directly to the appropriate officials in other governments, with copies of the notices provided to the State Department to keep them informed about the communication.

(c) *Comments.* All commentors except one supported the direct transmittal of section 17(b) notices. The commentor who opposed EPA's direct transmittal of the notices stated that since the statute requires EPA to go through the State Department in transmitting notices, they could not condone EPA's proposal to act on discretionary authority and not follow the explicit statutory provision.

(d) *Response.* EPA will continue to send section 17(b) notices to the State Department for transmittal to embassies. In addition, EPA will send advance notices of actions covered by section 17(b) requirements directly to the appropriate officials in other governments. EPA will also prepare an annual summary of actions covered by section 17(b). EPA will send the annual summary of actions directly to appropriate officials in other governments and simultaneously to the State Department.

**4. Content and format of the section 17(b) notices.** The section 17(b) notices currently contain a summary of the action taken, an explanation of the health or environmental reasons prompting the action, and the legislative and regulatory background for the action. The notices state that additional information is available upon request, usually in the form of a technical support document or fact sheet. There is no current standardized format for section 17(b) notices.

a. *1990 proposal.* In the proposed policy statement, EPA proposed expanding the content of the section 17(b) notifications and solicited comment on the kinds of information which should be included in the notices and the appropriate format, particularly for the annual summary that will include listings of all actions taken during a calendar year. EPA stated that it intends to comply with recommendations for formats made by international organizations when revising the EPA notices, and requested comments on this point.

b. *Comment.* The Agency received few comments on this issue. Two commentors stated that the information in section 17(b) notices should be easily understood, not just a copy of the Federal Register notice describing the action. In addition, the same commentors agreed with EPA's proposal to follow an internationally agreed upon format, when possible. Three commentors suggested including the name, address, telephone and Facsimile (FAX) number of EPA contacts with the notice.

c. *Response.* EPA agrees with all comments on this issue. EPA believes it would be useful to expand the information contained in section 17(b) notices. For example, in some cases more information about alternative pesticides, handling, storage and disposal could be provided. EPA has

decided to expand the information it includes in section 17(b) notifications to the extent it is available, and consistent with the need for prompt notification. EPA is also considering providing Spanish and French translations of section 17(b) notices upon request. (English, Spanish, and French are the official languages FAO/UNEP will use in implementing PIC notification procedures.)

EPA plans to incorporate, to the extent possible, some of the information used in the FAO/UNEP notification of control action form for section 17(b) notifications. EPA will clearly indicate that the notice is pursuant to section 17(b) of FIFRA, so as not to confuse the recipient. The FAO/UNEP form includes the following information: the Chemical Abstract System registry number of each active ingredient, trade names and the chemical nomenclature used by the International Union of Pure and Applied Chemists (IUPAC), a description of the regulatory action to ban or severely restrict the active ingredient and a reference to the national document ordering such action, a description of reasons for the action relevant to protection of health and the environment, and a discussion of known alternatives.

EPA will also notify the FAO/UNEP Secretariat, using notification of control action forms, of all final actions which meet the internationally-agreed upon definitions of "banned or severely restricted for health or environmental reasons." This will place all relevant information into an international data base and information exchange procedure.

#### E. Section 17(d) Activities

1. *Prior Informed Consent System.* In 1989, FAO and UNEP jointly adopted procedures to augment their existing guidelines for notification and information exchange among countries. The procedures are known as Prior Informed Consent (PIC) for trade in pesticides and industrial chemicals which have been banned or severely restricted (57 FR 58390, December 9, 1992). FAO will manage the program for pesticides, while UNEP will manage the program for industrial chemicals. The information exchange system, of which PIC is a part, also includes procedures for information exchange on regulatory actions which do not fall within the definitions of banned or severely restricted.

The primary objective of the PIC procedure is to establish a system in which participating importing countries will get information concerning chemicals whose use is banned or severely restricted in other countries; decide whether to allow, restrict, or stop the future imports of such chemicals; and notify other countries on a formal basis of their decision concerning importation and use. The fundamental principle of the PIC system is that international shipment of a chemical that is banned or severely restricted in order to protect human health or the environment should not proceed without the agreement or

contrary to the decision of the designated national authority in the importing country.

The PIC procedures require that countries banning or severely restricting a pesticide or industrial chemical for health or environmental reasons (including voluntary withdrawals and refusal to grant first registration when these actions are taken for health or environmental reasons) notify the FAO/UNEP joint program.

All participating countries will receive information on the health or environmental reasons why bans or severe restrictions have been placed on the use of chemicals or pesticides. Upon request, they may also receive further information and/or technical assistance that may be helpful as they make a decision regarding continued use in their countries. Participating importing countries then notify FAO/UNEP of their decisions on whether the import of a PIC chemical will be allowed in the future, and if so, under what conditions. The PIC system provides a mechanism for formal dissemination of the decisions of importing countries to exporting countries. Exporting countries are requested to share the responsibility for controlling the export of such chemicals, and to communicate the decisions of participating importing countries to their export industries.

The United States is a strong supporter of the PIC procedures. In the February 12, 1990 proposal, EPA requested comment on how best to facilitate industry compliance with PIC under FIFRA, which as noted above, provides limited authority for EPA to prohibit pesticide exports if section 17 labeling and notification requirements are met. EPA received two comments on this issue. One country, and one private group commented that self-policing or self-auditing techniques would not be adequate to ensure shipments do not occur contrary to the decisions of importing countries. One of the commentators stated that statutory obligations, supported by official inspections and audits are necessary to ensure compliance with PIC.

EPA agrees that FIFRA should be amended to provide EPA with statutory authority to implement PIC fully with respect to United States pesticide exports. Acknowledging that under current FIFRA authority, the Agency has limited authority to prohibit pesticide exports, EPA intends to implement the PIC system as fully as possible, consistent with U.S. law.

On December 9, 1992, EPA published a Federal Register notice announcing the Agency's participation in the PIC procedures, and discussing EPA's submission of two lists of chemicals which are either banned or severely restricted in the United States. The notice also discusses EPA's plan to hold a public forum to discuss U.S. involvement—that of government, industry, and the public—in the PIC process, as well as the Agency's international notification programs under FIFRA and TSCA. (57 FR 58390.)

#### 2. Consistency between section 17(b) notifications and PIC implementation.

Generally, EPA's section 17(b) notification program covers a much broader range of regulatory actions than the notices which countries will be required to submit under the PIC procedures. The PIC system focuses on two categories of regulatory actions: pesticides and industrial chemicals which are "banned" or "severely restricted."

The FAO *International Code of Conduct on the Distribution and Use of Pesticides* defines "banned" as "a pesticide for which all registered uses have been prohibited by final governmental regulatory action, or for which all requests for registration or equivalent action for all uses have, for health or environmental reasons, not been granted."

The *Code of Conduct* defines "severely restricted" as "a limited ban-a pesticide for which virtually all registered uses have been prohibited by final governmental regulatory action but certain specified registered uses remain authorized."

Countries are not to report on proposed actions. Only pesticides and industrial chemicals which have been banned or severely restricted by a final government action, or due to voluntary cancellation by industry, may be listed. (However, voluntary cancellations should only be reported to FAO/UNEP where there is clear evidence that the pesticide is withdrawn for health and/or environmental reasons.)

EPA plans to review draft section 17(b) notices as they arise to see whether the actions described in the notices would also trigger notification under the PIC system. EPA has considered whether notification through the PIC procedures can or should substitute for direct notification to foreign governments of section 17(b) notices. EPA believes that allowing this substitution in those cases where the regulatory action described in the section 17(b) notice would also trigger a PIC notice will reduce the burden and cost to EPA and avoid possible confusion to those receiving and managing duplicative information. Therefore, the Agency intends to use PIC procedures to transmit notices to countries participating in PIC who have established a designated national authority on the FAO/UNEP list, rather than send duplicative section 17(b) notices.

For countries which do not have a designated national authority, EPA will obtain information on the appropriate person to contact and transmit section 17(b) notices as described in this final policy statement.

3. *Supporting environmental protection in other countries.* EPA's efforts to assist in the protection of public health and the environment in other nations follow two tracks. First, EPA provides information through the notification programs mandated by FIFRA section 17. Secondly, EPA supports the development of decision-making



capabilities and regulatory infrastructures in pesticide importing countries.

There are many ongoing projects designed to assist the development of effective pesticide regulatory systems and to promote safer pesticide use in developing countries.

One example is EPA's work with the U.S. Agency for International Development (AID) to develop a comprehensive pilot program to improve pest and pesticide management in Central America. The overall goals of the project are to enhance public health, environmental protection and food safety in both the United States and Central American countries. The project will be coordinated with ongoing activities under the auspices of FAO to establish an international system of information exchange and "prior informed consent" with respect to international trade in pesticides and other efforts to strengthen the regulatory capabilities of developing countries.

Collaboration between EPA and AID will focus on the following three areas:

- (a) Strengthening Regulatory Institutions by providing training, technical assistance, and information to the Central American national and regional entities involved in the regulation of pesticide importation, distribution, use and disposal.
- (b) Support for AID Food Export Programs by providing information that will assist Central American countries in meeting U.S. pesticide tolerance requirements.
- (c) Pesticide management and safety training, including the development of training and technical assistance programs designed to promote and encourage the adoption of appropriate pest management practices.

In connection with the development of the pilot project, EPA organized and conducted a workshop with AID in San Jose, Costa Rica in November 1990. The workshop focused on the U.S. pesticide regulatory system, with the aim of familiarizing Central American countries with regulatory requirements and procedures, particularly as they apply to foods intended for export to the United States. The Agency for International Development, the U.S. Food and Drug Administration, and the U.S. Department of Agriculture all participated.

Another component of the Central American project is the development of joint FDA-EPA laboratory assessment and enhancement activities, which will include a survey of current laboratory capabilities in the region, technical assistance and training in analytical methods and quality control, access to pesticide reference standards, and other forms of technical cooperation.

During 1991, EPA officials participated in interagency meetings with Mexican governmental officials in Mexico City and in Washington, DC to exchange information on regulatory procedures as well as specific chemicals of concern, to discuss plans for upgrading pesticide regulation and

enforcement, and to explore proposals for reducing violative residues on food imported into the United States.

In 1990, EPA, at the request of AID and USDA, participated in a AID-organized disposal workshop for West African countries in Niamey, Niger. The focus of the workshop was mitigation of environmental problems resulting from storage and disposal of pesticides. In 1990, EPA provided technical assistance in storage and disposal to Guinea Bissau.

Other examples of EPA's recent international pesticide activities include: co-sponsorship of regional workshops with the United Nations' FAO, on strengthening pesticide regulation in Asia and the Pacific Islands, Latin America and the Caribbean; participation in an international meeting in Beijing, China, on international harmonization of pesticide tolerance levels; and numerous other international technical meetings. EPA continues to host numerous international visitors to provide training in a variety of areas, including regulatory development, data evaluation, decision methods and procedures for pesticide regulation; and to provide expert staff participation in international workshops and technical assistance activities.

EPA has also developed projects jointly with the U.S. Peace Corps. Through a Memorandum of Understanding (MOU) signed with the U.S. Peace Corps in September of 1989, EPA has provided technical assistance through the provision of EPA expert trainers and training materials and participation in training needs assessments. EPA participated in an assessment of pesticide use and regulation in Ecuador and Paraguay, particularly with respect to the Peace Corps volunteer sites and positions. In 1990, EPA conducted training on pesticide safety for 28 Peace Corps volunteers in Ecuador, and provided bilingual training materials on pesticide application and safety, for this and future training.

**4. Harmonizing U.S. and international standards.** EPA recognizes that protecting the global environment and the public health of all peoples must be a truly cooperative international effort. Through participation in the activities of international organizations, EPA promotes the development of consistent methods and standards to meet these common objectives. Encouraging the development of pesticide standards which promote effective environmental and public health protection world-wide also serve to minimize unnecessary disruption of international trade. While EPA recognizes that environmental regulation which is not based on sound science and risk management policy should not be used to enact unfair trade barriers, EPA will not relax science-based standards which protect public health or the environment in order to harmonize them with standards established elsewhere.

EPA participates in activities aimed at promoting harmonization of science-based pesticide regulatory requirements and resolving problems that may result from differing standards that may raise allegations of unjustified restrictions on international trade. Examples of these activities are: the provision of information on proposed regulatory actions (e.g., cancellations, suspensions, tolerances or tolerance revocations); EPA's participation in the General Agreement on Trade and Tariffs (GATT) Uruguay Round negotiations on sanitary and phytosanitary measures; discussions in connection with the negotiation of a North American Free Trade Agreement; the Rome Conference on Food Standards, Chemicals in Food and Trade, (an international meeting jointly sponsored by FAO and the World Health Organization (WHO) in March 1991); and in numerous FAO expert meetings and Government Consultations. In addition, EPA actively supports the Joint Meeting on Pesticide Residues (JMPPR) and the Codex Committee on Pesticide Residues (CCPR), providing resources and temporary expert advisors to assist in scientific deliberations. EPA also participates in periodic meetings with its counterparts in Canada, the United Kingdom, and the European Community to discuss pesticide regulation and food safety issues.

#### IV. Technical Amendment

##### A. Revising Section 169.2(h)(3) to Conform With the Requirements of this Policy

Section 169.2(h) contains recordkeeping requirements for exporters of pesticides, devices, and active ingredients used in producing pesticides intended solely for export to any foreign country. The second sentence of paragraph 3 of section 169.2(h) discusses the requirement to obtain a foreign purchaser acknowledgement statement pursuant. EPA is deleting this sentence in order to make section 169.2(h) consistent with this policy.

#### V. Public Record

EPA has established a public record for this final policy statement under docket number OPP-170003. Included in the record are two proposed policies (dockets number OPP-170000 and 170001), as well as copies of public comments received on the proposed policy statements. The record is available for inspection in Room 1128, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, Virginia.

#### VI. Other Regulatory Requirements

##### A. Executive Order 12991

Under Executive Order 12991, EPA must judge whether an action is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this policy does not constitute a major action because it does not meet any

of the criteria set forth and defined in section 1(b) of the Order. Costs were estimated based on existing program experience, including the number of annual submissions presently made to EPA that would be affected by changes.

This policy was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments from OMB to EPA and any EPA response to those comments are available for public inspection in the public file at the Public Docket location listed under the Public Record section cited above.

#### B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, (5 U.S.C. 605(b)), EPA has determined that this policy will not have a significant economic impact on a substantial number of small businesses. The recordkeeping required would easily be satisfied by the normal invoices that are a necessary part of all overseas transactions. The purchaser acknowledgement statements required to be signed could be included with sales contracts signed by the foreign purchaser. The cost of reporting to the Agency as shown in the information collection burden statement is minimal. A requirement that the purchaser acknowledgement statement be multilingual was not included in the final policy for a number of reasons, including comments that the cost to small businesses could be prohibitive.

#### C. Paperwork Reduction Act

This policy amends provisions of the foreign purchaser acknowledgement statement requirement of the export policy for unregistered pesticides, which is currently cleared by the Office of Management and Budget (OMB) under control number 2070-0027. The information collection requirements imposed by this policy statement have been submitted to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. A copy of the information collection request (ICR) document may be obtained from the Information Policy Branch of the Office of Policy, Planning and Evaluation (OPPE) of EPA at the address given below.

Annual respondent burden for this collection of information is estimated to average .92 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An estimated 976 responses annually are anticipated, for a total annual burden of 895 hours. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, and to the Office of Information and Regulatory Affairs, Office of

Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

#### List of Subjects 40 CFR Parts 168 and 169

Advertising, Exports, Labeling, Pesticides and pests, Policy statements, Reporting and recordkeeping requirements.

Dated: January 19, 1993.

William K. Reilly,  
Administrator.

Therefore, 40 CFR chapter I, parts 168 and 169 are amended as follows:

#### PART 168 [AMENDED]

In part 168;

a. The authority citation for part 168 continues to read as follows:

Authority: 7 U.S.C. 136-136y.

#### SUBPART C [RESERVED]

b. Subpart C is added and reserved.

3. Subpart D is added to read as follows.

#### Subpart D—Export Policy and Procedures for Exporting Unregistered Pesticides

Sec.

168.65 Pesticide export label and labeling requirements.

168.75 Procedures for exporting unregistered pesticides—purchaser acknowledgement statement requirement.

168.85 Other export requirements.

#### § 168.65 Pesticide export label and labeling requirements.

(a) *General.* This section describes how EPA interprets and will enforce the requirements of FIFRA section 17(a)(1). Every exported pesticide, device, and active ingredient used in producing a pesticide (see § 152.3 of this chapter for the definition of "active ingredient" and "pesticide") must bear a label or labeling which meets the requirements of FIFRA section 17(a)(1). This requirement applies to all such pesticides, devices, or active ingredients, regardless of whether the export is for commercial or research use. In the case of unregistered pesticides, including research substances which are being exported for testing, the labeling requirements of this section continue to apply independently of whether the exporter must submit a purchaser acknowledgement statement under FIFRA section 17(a)(2) as described at § 168.75 of this chapter. In addition, information which will satisfy FIFRA section 2(q)(1)(E), (G), and (H) and section 2(q)(2)(A) and (D) must appear in English and in the appropriate foreign languages, on the label or labeling as described in paragraph (b)(4) of this section. The required label and labeling statements may be met through either immediate container labels, accompanying supplemental labeling as described in paragraph (c) of this section, or a combination of the two.

(b) *Specific requirements.* The labels and labeling of any exported pesticides, devices, and active ingredients used in producing pesticides must meet the requirements regarding label and labeling content, correct representation, and understandability as stated in this paragraph.

(1) *Label contents.* The term "label" means the written, printed, or graphic matter on or attached to the immediate container of the pesticide, device, or active ingredient used in producing a pesticide. In the case that the immediate container is enclosed in an outer container or wrapper through which the label cannot be read, the label must also be on such outer container or wrapper. Except as provided in paragraph (c) of this section, the immediate container of the pesticide, device, or active ingredient used in producing a pesticide must bear a conspicuous and readable label which includes:

(i) *EPA pesticide producing establishment number.* The producing establishment registration number must be present but may appear anywhere on the label or immediate container in accordance with the establishment registration labeling requirements set forth in § 156.10(f) of this chapter.

(ii) *Warning or caution statements.* Warning or caution statements must appear on the label and must be adequate for the protection of persons handling the pesticide, device, or active ingredients including warnings regarding general toxicological hazards and environmental, physical, or chemical hazards. Warning and caution statements must appear in English and in the appropriate foreign languages, as described in paragraph (b)(4) of this section. Where the U.S. warning or caution statement, as translated, is obviously inappropriate to protect residents of the importing country, (for example, where a statement calls for a gas mask meeting the specification of the U.S. Bureau of Mines) an equivalent caution must be substituted.

(iii) *The statement "Not Registered for Use in the United States of America."* The labels of all pesticides, devices, and active ingredients which are not registered for use in the United States under FIFRA section 3 must prominently display the following statement: "Not Registered for Use in the United States of America." The statement must appear in English and in appropriate foreign languages, as described in paragraph (b)(4) of this section. It is permissible to append explanatory text which qualifies the statement by pointing out the reasons for the unregistered status. Examples of possible additional statements are "Not Registered for Use on...", "No Longer Registered for Use...", or "Not Registered...because..." Such additions must not be misleading or misrepresent the registration status of the pesticide. The statement "Not Registered For Use in the United States of America" must also be present.

(A) A pesticide is considered registered for the purposes of the section 17(a)(1) requirement only when:

(1) A label and labeling approved under a current FIFRA section 3 registration for the product is either attached to the immediate product container or accompanies the product at all times as supplemental labeling as provided in paragraph (c) of this section.

(2) The formula of the exported product is the same as the formula of the U.S. registered product (within certified limits). In addition, a change in the color or fragrance of the export product will not affect the product's registration status, as long as the following conditions are met:

(i) The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at § 180.1001, and the dye must not be a List 1 inert. (List 1 inerts are those inerts which the Agency has identified as presenting toxicological concerns. The classification of inerts is explained in EPA's Policy Statement on Inert Ingredients in Pesticide Products, which can be obtained from the Office of Pesticide Programs public docket, Room 1128, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202.

(ii) The change in fragrance must result only from the addition of a chemical included on the list of chemicals exempted from the requirement of a tolerance (§ 180.1001) and the chemical must not be a List 1 inert.

(iii) The change in fragrance must not result in a pesticide product containing a food or food-like fragrance. (See "Food Fragrances in Pesticide Formulations," EPA's Office of Pesticide Programs Policy and Criteria Notice number 2155.1, November 20, 1975 which can be obtained from the Office of Pesticide Programs public docket, Room 1128, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, Virginia 22202.)

(iv) Any differences in color or fragrance of the export product in accordance with this section must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(3) No statements which appear on any of the product labels or labeling add new uses or claims or in any way contradict the approved FIFRA section 3 labeling. However, certain minor changes may be made to a product's labeling or packaging without affecting the registration status of the product, as specified in § 152.46(b) of this chapter.

(iv) *The ingredient statement.* The ingredient statement must appear on the label in English and in appropriate foreign languages (as described in paragraph (b)(4) of this section). If the English language description of the ingredients is easily identifiable and likely to be understood by the ordinary individual, the foreign language ingredient statement need not be included on

the label. In the case of pesticide products, devices and active ingredients shipped solely for research and development purposes, it is permissible to use coded identification of ingredients on the label in order to protect confidentiality, in accordance with the requirements of §§ 168.75(c) and 168.85(a).

(v) *Identity of parties.* The name and address of the producer, registrant (if any), or the person for whom the pesticide was produced, must appear on the label.

(vi) *Weight or measure.* The net weight must appear on the label in either English or metric units.

(vii) *Additional warning for highly toxic pesticides.* If the pesticide, device or active ingredient is highly toxic to humans, the skull and crossbones, the word "Poison", and a statement of practical treatment must appear on the label. The word "Poison" and the statement of practical treatment shall be in English and in the appropriate foreign languages, as described in paragraph (b)(4) of this section. The skull and crossbones may be in red or black. For criteria on what pesticides are highly toxic, see § 156.10(h) of this chapter.

(2) *Use classification statement.* In addition to the label contents described in paragraph (b)(1) of this section, the labeling must include a use classification statement, if a use classification has been assigned under a FIFRA section 3 registration. The use classification shall accurately describe the use classification applicable to the U.S. registered use of the pesticide, device or active ingredient (e.g., "Restricted Use Pesticide"). Summary statements describing the use classification, e.g., "For retail sale to and use only by Certified Applicators..." or explaining what such terms mean are not required, but may be included if such statements do not result in false representation of the U.S. regulatory status of the pesticide. The use classification information may appear on the product label or on the labeling accompanying the pesticide product during shipment.

(3) *Misrepresentation.* The labeling shall not make false or misleading representations or represent the product as an imitation of other products.

(4) *Understandability.* The required statements must be expressed in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use. To satisfy this section, certain information described in paragraph (b)(4)(i) of this section, which appears on the labeling of all exported pesticide products, devices and active ingredients must appear in English, in an acceptable language of the country of import as defined in paragraph (b)(4)(ii) of this section, and in an acceptable language of the country of final destination, if known or reasonably ascertainable by the exporter. When there are several official languages or dialects in a country, the language which is

predominately spoken or written, or a language in which official government business is conducted, will be acceptable.

(i) *Information required to be multilingual.* The following labeling information must be multilingual:

(A) The warning and caution statements.

(B) Where required, the statement "Not Registered for Use in the United States of America."

(C) The ingredient statement.

(D) Where required in accordance with paragraph (b)(1)(vii) of this section, the word "Poison" and the statement of practical treatment in case of poisoning.

(ii) *Acceptable languages.* In all cases, English must be one of the languages used on the label or labeling. In addition, either the language which is used to conduct official government business, or the predominantly spoken or written language of the country of import must appear on the labeling. In each case where a country of final destination is known, the language which is used to conduct official government business or which is predominantly spoken in that country, if different from the language of the country of import, shall also appear on the labeling. In any case where English is predominantly spoken or written or is the language used to conduct official government business in a country, no other language need be included to meet the multiple language requirement of this paragraph.

(c) *Supplemental labeling.* A pesticide, device or active ingredient intended for export will not be considered in violation of the labeling requirements of FIFRA when the label and/or labeling requirements stated in paragraph (b) of this section are met by supplemental labeling. Supplemental labeling must be attached to the immediate product container or the shipping container of the pesticide, device or active ingredient at all times when it is shipped or held for shipment to meet export label requirements.

Supplemental labeling must meet all of the label requirements in paragraph (b) of this section which are not met by the immediate product labels. Supplemental labeling will satisfy the labeling requirements of FIFRA only if the following conditions are met:

(1) *Applicability.* The use of supplemental labeling applies to any situation where the labeling requirements specified in this section are not met fully on the product label which is attached to the immediate product container. Any required label or labeling statement not met on the immediate container may be met through supplemental labeling.

(2) *Labeling contents and relation to shipment.* If supplemental labeling is used to meet any of the labeling requirements of FIFRA section 17(a)(1), it must meet all of the requirements in paragraph (b) of this section which are not met by the label on the immediate product container. Thus, the supplemental labeling, together with the immediate product container label will meet

all of the requirements of paragraph (b) of this section. Where used, supplemental labeling must be attached to or accompany the product shipping container of the pesticide, device, or active ingredient used in producing a pesticide at all times when shipped or held for shipment in the United States.

**§ 168.75 Procedures for exporting unregistered pesticides—purchaser acknowledgement statements.**

This section describes how EPA interprets and will enforce requirements of FIFRA section 17(a)(2). Section 17(a)(2) provides that any person exporting a pesticide other than a pesticide registered for use under FIFRA section 3 or sold under FIFRA section 6(a)(1), shall obtain a statement signed by the foreign purchaser prior to export, acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States. Section 17(a)(2) requires that a copy of the statement be transmitted to an appropriate official of the government of the importing country.

(a) *Products subject to the requirement.* EPA will not consider an exporter of an unregistered pesticide to be in violation of FIFRA section 17(a)(2) if, prior to export of the pesticide, the exporter submits to EPA a statement signed by the foreign purchaser which affirms that the purchaser is aware that the pesticide is not registered for use in the United States and cannot be sold for use in the United States. The exporter must also include with the submission of the purchaser acknowledgement statement to EPA, a certification signed by the exporter affirming that the export did not occur until the statement signed by the foreign purchaser was obtained by the exporter. Except as provided in paragraph (b) of this section, all pesticide products produced for export which cannot be sold for use in the United States in the form that they are produced for export, are considered to be unregistered pesticides. This includes pesticides which are of a different formulation, including composition (except for variation within certified limits), or type of formulation, and pesticides which are packaged for use patterns for which they are not registered, which may be evidenced by package type or label use statements. This also includes unregistered products which are under development as pesticidal products and which are being exported for research testing.

(b) *Exceptions.* Under the specific circumstances discussed below, EPA will not treat a registered product which has been modified slightly for export purposes, as unregistered for the purposes of the purchaser acknowledgement statement requirement. Any changes to the registered product for export purposes must be documented in accordance with the record-keeping requirements at § 169.2 of this chapter and this policy.

(1) *Labeling on Immediate Product.* EPA will not treat as unregistered for the purposes of section 17(a)(2), a registered pesticide product which cannot be sold or distributed for use in the United States because its immediate product container does not bear a label approved under a FIFRA section 3 registration, but which could be sold or distributed in the United States with the approved label attached to the immediate product container, provided that the label and labeling approved under a current FIFRA section 3 registration for the product is either attached to the immediate product container or accompanies the product at all times as supplemental labeling as provided in paragraph (c) of this section.

(2) *Packaging.* (i) Certain changes may be made to a product's labeling or packaging without affecting the registration status of the product, as specified in § 152.46(b) of this chapter and this policy. These changes include any changes in package size and label net contents, provided no change in use directions or requirement for child-resistant packaging would be necessary for the product to be registered for use in the United States. For example, if child-resistant packaging is required for a particular pesticide product in the United States, and the product will be exported without child-resistant packaging, the product would be considered unregistered and therefore subject to all the requirements of FIFRA section 17(a), as described in § 168.75 of this chapter including the requirement for a purchaser acknowledgement statement.

(ii) If an exporter needed to repackage a product in a size to meet a foreign purchaser's specifications, that modification would not affect the registration status of the export product. Other modifications to the label used for export purposes which will not affect the export product's registration status are: the use of metric units for net contents, dosages, and other numeric expressions; the use of a different format for the label, provided that the information does not contradict the U.S. label; revision of non-mandatory U.S. label statements, consistent with 40 CFR part 156, including additions or changes required by other Federal statutes or regulations; a change of the name or address of the registrant, except for a change resulting from transfer of ownership, which requires that a registrant keep his name and address current with the Agency; and any correction of typographical or printing errors that appeared on the U.S. labeling. (See § 152.46(b)).

(3) *Labeling statements.* The following statements which appear on any of the product labels or labeling will not affect the status of the product, provided that they do not contradict the approved FIFRA section 3 labeling:

(i) It is permissible to add explanatory language which accurately explains the meaning of a use classification. For example,

the statement "restricted use pesticide" may be expanded to read: "Restricted in the United States of America to use by certified applicators" or "Restricted Use Pesticide. In The United States this product is restricted to use by applicators determined by each state to be competent in pesticide application and the human health and environmental consequences of misuse." If the explanatory language falsely represents or is misleading regarding the U.S. use classification, the product will be considered misbranded. In addition, a use classification can only be listed if one has been assigned pursuant to the U.S. registration.

(ii) An exporter who is also the manufacturer of a U.S. registered pesticide may add new uses to the label of that product for export purposes, without triggering the requirements of section 17(a)(2), as long as the new uses are within the same general use patterns as those for the registered product. (Pesticide use patterns are listed in Appendix A to 40 CFR part 158—Data Requirements for Registration: Use Pattern Index. The general pesticide use patterns are: terrestrial food crop and terrestrial nonfood crop; greenhouse food crop and greenhouse nonfood crop; aquatic food crop and aquatic nonfood crop; indoor use; and forestry use.) Adding new uses to the label which change the use pattern, such as changes from non-food to food use, outdoor to indoor use, or terrestrial to aquatic use, render the product unregistered and subject to the requirements of section 17 for unregistered products. If the new use added to the label is a food or feed use, a tolerance must already be established for the use of that pesticide in or on that commodity.

(4) *Composition.* EPA will not treat a registered product as unregistered for the purposes of the purchaser acknowledgement statement requirement under the following specific circumstances:

(i) The formula of the exported product is within certified limits of the formula of the U.S. registered product.

(ii) An exporter, who is also the manufacturer of a U.S. registered pesticide, may decrease the percentage of the active ingredient(s) of that product by adding a List 4 inert ingredient, without causing the product to be treated as "unregistered" and triggering the requirement to obtain a purchaser acknowledgement statement as a condition for export. In EPA's Policy Statement on Inert Ingredients in Pesticide Products, EPA included inert ingredients on List 4—a list of inert ingredients posing minimal hazard or risk—if the inert ingredients were generally regarded as innocuous. The provisions of this paragraph do not apply to those pesticide products intended for public health uses which are required or conditionally required to submit efficacy data pursuant to § 158.640 of this chapter. Any differences in formula or composition caused by adding a List 4 inert must be reflected in records which show the complete formula of the export product in

accordance with the requirements of § 169.2 and this policy.

(iii) A change in the color or fragrance of the export product will not affect the product's registration status as long as the following conditions are met. The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at § 180.1001, and the dye must not be a List 1 inert. (List 1 inerts are those inerts which the Agency has identified as presenting toxicological concerns. The classification of inerts is explained in EPA's Policy Statement on Inert Ingredients in Pesticide Products. The change in fragrance must result only from the addition of a chemical included on the list of chemicals exempted from the requirement of a tolerance (§ 180.1001) and the chemical must not be a List 1 inert. The change in fragrance must not result in a pesticide product containing a food or food-like fragrance. (See "Food Fragrances in Pesticide Formulations," EPA's Office of Pesticide Programs Policy and Criteria Notice number 2155.1, November 20, 1975.) Any difference in color or fragrance of the export product in accordance with this section must be reflected in records which show the complete formula of the export product in accordance with the requirements of § 169.2 and this policy.

(5) *Research and development products.* An unregistered pesticide product exported only for research and development purposes is subject to the notification requirements of this section, unless its use fits within the criteria described in this paragraph.

(i) An unregistered pesticide product exported solely for research and development purposes will not be considered to be in violation of the notification requirements if the export of the research and development product:

(A) Would not involve land uses of more than 10 acres (4.05 hectares), or be used on or affect food or feed crops which are intended for consumption.

(B) Would not involve aquatic uses of more than 1 acre (0.405 hectares), or any aquatic uses which involve water used for irrigation, drinking or recreation, or be used on or affect plants or animals taken for food or feed from such waters.

(C) Would not involve tests on animals intended for food or feed.

(ii) Shipments to different purchasers, to different countries of final destination, or which occur more than a calendar year apart will be evaluated separately. When determining whether total shipments exceed the criteria described in this paragraph, EPA will evaluate the total amount of shipments by a single exporter during a calendar year for use in a particular country.

(iii) An exporter bears the burden of demonstrating that the product meets these criteria before the research product is shipped. This may be met by documenting before the

product is shipped and maintaining records for the time period required by § 169.2(h) of this chapter from the date of the last shipment relevant to such records. The records to be maintained consist of:

(A) The identity of the purchaser and country of intended use of the research product.

(B) The amount shipped.

(C) The intended research use by the purchaser, including the type of application site, rate of application, and measures taken for protection of humans from direct or dietary exposure.

(c) *Procedures.* An exporter of an unregistered pesticide product must submit a purchaser acknowledgement statement to EPA containing the information stated in paragraph (c)(1) of this section, and a statement signed by the exporter certifying that the exportation did not occur until the signed acknowledgement statement had been obtained from the purchaser. If the foreign purchaser signs a purchaser acknowledgement statement in their own language, it must be accompanied by an English translation when it is submitted to EPA by the exporter. These statements shall be submitted in accordance with one of the two options for submission described in paragraph (c)(2) of this section.

(1) *Contents of the purchaser acknowledgement statements.* The purchaser acknowledgement statement must include the following information in a format that is clearly understandable:

(i) Name, address, and EPA identification number, if applicable, of the exporter.

(ii) Name and address of the foreign purchaser.

(iii) Identity of the product and the active ingredient(s), including:

(A) The Chemical Abstract Services (CAS) Registry number for each active ingredient.

(B) The chemical nomenclature for each active ingredient as used by the International Union of Pure and Applied Chemists (IUPAC).

(C) Other known chemical or common names; or if the export involves a research product, a code name or identification number that can be used by EPA to identify the product from the exporter's records. If a code name or identification number is used, additional information must be attached to the certification statement submitted with the purchaser acknowledgement statement which will enable EPA to identify the product. This attached information may be claimed as confidential, and EPA will not forward this information with the purchaser acknowledgement statement to foreign governments.

(iv) If known or reasonably ascertainable, the country or countries of final destination of the export shipment, i.e., where the exported pesticide is intended to be used, if different from the country of the foreign purchaser's address.

(v) A statement that indicates that the foreign purchaser understands that the product is not registered for use in the United States and cannot be sold in the United States.

(vi) The signature of the foreign purchaser.

(vii) The date of the foreign purchaser's signature.

(2) *Reporting options.* At the discretion of the exporter, the requirements of paragraph (c)(1) of this section may be met on a per-shipment or annual basis, as stated in paragraphs (c)(2)(i) and (c)(2)(ii) of this section. If the procedures in paragraph (c)(2)(ii) of this section are not followed, EPA will consider paragraph (c)(2)(i) of this section, requiring per-shipment purchaser acknowledgement statements, to be applicable in full. Where paragraph (c)(2)(i) of this section is applicable, each shipment which does not meet the requirements of that paragraph will be considered to be a separate violation of FIFRA.

(i) *Per-shipment purchaser acknowledgement statement.* Unless the exporter chooses to follow the procedures described in paragraph (c)(2)(ii) of this section for the annual reporting procedures, the exporter must obtain and submit to EPA, a signed purchaser acknowledgement statement prior to each shipment of an unregistered pesticide according to the following procedures:

(A) Prior to each shipment in a calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, the exporter must provide the foreign purchaser with instructions about the required information on a purchaser acknowledgement statement, and inform the foreign purchaser that the pesticide product cannot be exported from the United States until the exporter has received from the foreign purchaser a properly completed, signed, and dated acknowledgement statement.

(B) The exporter must obtain, prior to each shipment in a calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, a signed purchaser acknowledgement statement which contains the information set forth in paragraph (c)(1) of this section.

(C) The exporter must sign a statement certifying that export did not take place until a signed purchaser acknowledgement statement was received. The exporter must also specify the chemical identity of any research product which is referred to by code in the purchaser acknowledgement statement. The information regarding the specific identity of research products, which may be included in the statement or consist of an attachment to the certification, may be claimed as confidential.

(D) The exporter must submit the signed acknowledgement statement from the foreign purchaser, and the accompanying certification by the exporter including attachments, to EPA within 7 working days of the exporter's receipt of the purchaser acknowledgement

statement, or by the date of export, whichever occurs first. This information must be transmitted to the following address: U.S. Environmental Protection Agency, Office of Pesticide Programs, (H-7501C), 401 M Street, SW, Washington, DC 20460, Attention: Purchaser Acknowledgement Statement.

(ii) *Annual reporting procedures.* Unless the exporter chooses to follow the per-shipment reporting option described in paragraph (c)(2)(i) of this section, the exporter must follow the procedures for annual summary reporting which include the requirement of a purchaser acknowledgement statement for the first shipment each calendar year of an unregistered pesticide product to a particular purchaser, and an annual summary of shipments to that purchaser. The annual summary reporting procedures are as follows:

(A) Prior to the first shipment each calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, the exporter must provide the foreign purchaser with instructions about the required information on a purchaser acknowledgement statement, and inform the foreign purchaser that the pesticide product cannot be exported from the United States until the exporter has received from the foreign purchaser a properly completed, signed, and dated purchaser acknowledgement statement.

(B) The exporter must obtain, prior to the first shipment each calendar year of an unregistered pesticide product to a particular purchaser in a foreign country, a signed purchaser acknowledgement statement which contains the information set forth in paragraph (c)(1) of this section.

(C) The exporter must sign a statement certifying that export did not take place until a signed purchaser acknowledgement statement was received, indicating that this statement is for the first shipment to a particular purchaser in a specific country for that calendar year, and that the exporter will meet all the purchaser acknowledgement statement requirements as described in this paragraph (c)(2)(ii) of this section. The exporter must also specify the chemical identity of any research product which is referred to by code in the purchaser acknowledgement statement. The information regarding the specific identity of research products, which may be included in the statement or consist of an attachment to the certification, may be claimed as confidential.

(D) The exporter must submit the signed acknowledgement statement from the foreign purchaser, and the accompanying certification by the exporter including attachments, to EPA within 7 working days of the exporter's receipt of the purchaser acknowledgement statement, or by the date of export, whichever occurs first. This information must be transmitted to the following address: U.S. Environmental Protection Agency, Office of Pesticide Programs, (H-7501C), 401 M Street, SW,

Washington, DC 20460, Attention: Purchaser Acknowledgement Statement.

(E) The exporter, who has chosen to comply with the requirements of this paragraph instead of providing per-shipment purchaser acknowledgement statements in accordance with paragraph (c)(2)(i) of this section, must submit an annual summary report to EPA. An annual summary report is required for each unregistered pesticide exported within the preceding calendar year. The report must be in writing, signed by the exporter, and include the following information:

(1) Name, address, and EPA identification number if applicable, of the exporter.

(2) Name and address of the foreign purchaser, and the date the purchaser acknowledgement statement, submitted to EPA during the previous calendar year, was signed by the purchaser.

(3) The identity of the product and the active ingredients, including: the Chemical Abstract Services (CAS) registry number for each active ingredient, the chemical nomenclature for each active ingredient used by the International Union of Pure and Applied Chemists (IUPAC), and other known chemical or common names, or if the export involves a research product, the code name or identification number that can be used by EPA to identify the product from the exporter's records.

(4) The dates of each shipment of the pesticide exported to the foreign purchaser during that calendar year.

(5) If known, or reasonably ascertainable, the country or countries of final destination of the export shipments, i.e., where the exported pesticide was intended to be used, if different from the foreign purchaser's address.

(F) The exporter shall submit the annual summary no later than March 1st of the following calendar year. The annual summary shall be sent to the following address: U.S. Environmental Protection Agency, Office of Pesticide Programs, H-7501C, 401 M Street, SW., Washington, DC 20460, Attention: Annual Summary of Exports.

(iii) *Confidentiality claims.* Persons submitting the information specified in the purchaser acknowledgement statement may assert a claim of business confidentiality by marking the information claimed confidential as "FIFRA Confidential Business Information." Information so claimed will not be disclosed, with the exception of disclosure to the foreign governments, except in accordance with the procedures set forth in 40 CFR part 2, 7 U.S.C. 136(h), and this policy statement. If such claim is not asserted, EPA may disclose the information to the public without providing further notice prior to disclosure or an opportunity to object. Notwithstanding any claim of confidentiality, the purchaser acknowledgement statement will continue to be forwarded to the

appropriate foreign government officials in its entirety, as required by section 17(a)(2).

(3) *Recordkeeping.* Except as specifically stated, the requirement to retain records under part 169 of this chapter applies to all pesticide producers, regardless of whether a particular product is intended for export. All records shall be maintained in accordance with the time period required by § 169.2(h) of this chapter. Producers must also maintain certain records pertaining to pesticide products intended for export. In addition to the requirement that a copy of the purchaser acknowledgement statement be kept, as stated at § 169.2(h)(3) of this chapter, the following records must be maintained:

(i) Copies of the instructions provided to foreign purchasers in accordance with paragraphs (c)(2)(i)(A) and (c)(2)(ii)(A) of this section.

(ii) Copies of signed purchaser acknowledgement statements obtained according to paragraphs (c)(2)(i)(B) and (c)(2)(ii)(B) of this section.

(iii) Copies of the certification from the exporter; and copies of any accompanying information regarding the identity of coded R&D products.

(d) *Agency transmission of purchaser acknowledgement statements.* EPA will transmit a copy of each purchaser acknowledgement statement to the appropriate government official in each of the intended destination countries. After receipt of the Annual Summary the following calendar year, EPA will also transmit a copy of that document to the appropriate government official in each of the intended destination countries. In the case that no Annual Summary has been received within 30 days of the date at which such summary is required to be submitted, EPA will send written notification to the appropriate government official indicating that no summary was submitted, and may also take enforcement action against the exporter.

#### § 168.85 Other export requirements.

This section describes other requirements found in regulations that apply to exporters of pesticides, devices, and active ingredients used in producing a pesticide.

##### (a) *Recordkeeping and inspection.*

Exporters of pesticides, devices and active ingredients must keep records and permit inspections of those records in accordance with part 169 of this chapter. Exporters must keep records of the product labeling used, including the EPA registered labeling, any foreign labeling on or attached to the product when shipped, and, as applicable, any supplemental labeling used. Producers of pesticides for export shall maintain these records in a manner that shows exactly which labels and labeling accompanied each shipment of a pesticide product to a foreign country. As stated at § 168.75(c), when research product identity information appears on the labeling in an encoded manner,

information translating the code shall be maintained in records. These records shall be maintained for the time period required by § 169.2(h) of this chapter following the last export of such pesticides. All records required by part 169 of this chapter shall be made available for inspection and copying by EPA or its duly authorized representatives.

(b) *Pesticide production establishment requirements.* Exporters of pesticides, devices, and active ingredients must submit annual reports to EPA in accordance with part 167 of this chapter, concerning those products that are exported. All products required to be labeled "Not Registered for Use in the United States of America" must be reported

as unregistered production regardless of whether a purchaser acknowledgement statement is required.

#### **PART 169 [AMENDED]**

##### **2. In part 169**

a. The authority citation for part 169 continues to read as follows:

Authority: 7 U.S.C. 136f and 136w.

b. Section 169.2 is amended by revising paragraph (h)(3) and the flush text that immediately follows paragraph (h)(3) to read as follows:

##### **§ 169.2 Maintenance of records.**

(h)\* \* \*

(3) For any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of the Act, copies of a statement signed by the foreign purchaser of the pesticide acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act.

These records shall be retained for a period of 2 years after expiration of the contract.

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